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most recent revision release Operators Manual for this product.**

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constellation[®]
VISION SYSTEM

OPERATOR'S MANUAL

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FOREWORD

This Operator's Manual is designed to acquaint the operator and operating room personnel with the *Constellation*[®] Vision System. The manual presents an organized summary of the operating principles, main components, safety features, and instructions for care and use of the instrument.

The information in this manual should be supplemented with reference works on laser theory and the interaction of laser energy with biologic tissues. No attempt is made in this manual to answer all the questions that arise during the use of the instrument in medical procedures.

Questions concerning technique, safety and effectiveness should be referred to pertinent publications or recognized medical experts in laser surgery. Physicians should not attempt to treat patients with this instrument if not thoroughly familiar with its operation, or if in doubt as to its safe operation. All personnel authorized to use this instrument should be required to be thoroughly familiar with this manual.

Please contact Alcon for complete technical support and service if you have questions concerning any aspect of this instrument's operation or if it fails to perform satisfactorily.

To order supplies in U.S.A.:

800-862-5266

FAX: 800-241-0677

Outside U.S.A.: Contact your local Alcon representative for supplies.

IMPORTANT NOTICE

Equipment improvement is an on-going process and, as such, changes may be made to the equipment after this manual is printed.

Pay close attention to **WARNINGS** and **CAUTIONS** in this manual. **WARNINGS** are written to protect individuals from bodily harm. **CAUTIONS** are written to protect the instrument from damage. Illustrations contained in this manual are for reference only.

It is recommended that maintenance be performed by qualified Alcon Field Personnel.

Alcon Surgical shall not be liable for any damage resulting from failure to comply with the enclosed instructions.

Alcon reserves the right to change specifications without further notice.

Operator Profile

The *Constellation®* Vision System is designed to be operated by two basic groups; surgeons and nurses/scrub techs. The surgeon focus is primarily constrained to the footswitch and display panel. The design of the footswitch allows the surgeon to map any function to any switch position, assuming the function is valid in a particular scenario. The display screen was designed to mount on an articulating arm to allow optimum placement of the display so the surgeon can reference it at any time. The design also incorporates items specifically for nurses and scrub technicians, who routinely control the machine via the front panel and remote control. The design incorporates color coding on all connectors and tubing to facilitate easy identification of the ports. In addition, the graphical user interface closely resembles controls commonly found on web sites, which this operator profile is expected to be highly proficient at using.

CAUTION

U.S. Federal Law restricts this device to sale by or on the order of a physician only.

WARNINGS!

For systems containing the optional laser module: Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

A qualified technician must perform a visual inspection of the following components every twelve months. In case of a deficiency, do not use the system; call Alcon Technical Services.

- Warning Labels
- Power Cord
- Fuses

A qualified technician must check ground continuity and both polarities for leakage current every twelve months to ensure they are within the applicable standard (for example: IEC 60601-1). Values must be recorded, and if they are above the applicable standard, or 50% above your first measurement, do not use the system; call Alcon Technical Services.

Use of accessories and cables other than those provided may result in increased emissions or decreased immunity of the system. Portable and mobile RF communications equipment can affect this medical electrical equipment.

If you have questions, or want additional information, please contact your local Alcon representative or the Alcon Technical Services Department at:

Alcon Laboratories, Inc.
15800 Alton Parkway
Irvine, California 92618
(949) 753-1393
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SECTION ONE GENERAL INFORMATION

Introduction

The *Constellation®* Vision System is a multifunctional surgical instrument for use in anterior and posterior segment ophthalmic surgeries. The product's capabilities include driving a variety of handpieces that provide the ability to cut vitreous and tissues, emulsify the lens, illuminate the posterior segment of the eye, and apply diathermy to stop bleeding. Vacuum is used to remove ocular matter from the eye and is provided by connecting tubing from the handpiece to a port on the fluidics cassette. Irrigation/infusion capability is provided to replace fluid in the eye, and enters the eye directly through either an infusion cannula or a handpiece. The graphical operator interface is menu driven. The operator provides inputs using the touchscreen panel, the remote control, and the footswitch.

An optional, fully integrated laser module is available that can be installed in the base. The laser delivers a visible 532 nm green treatment beam designed for ophthalmic use.



Figure 1-1 The *Constellation®* Vision System - The *Constellation®* Vision System is a multifunctional surgical instrument used in anterior and posterior segment ophthalmic surgeries.

Indications for Use

The *Constellation®* Vision System is an ophthalmic microsurgical system that is indicated for both anterior segment (i.e. phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery in addition to the indications included with the optional Next Generation Laser (see laser indications on page 1.29).

System Configurations

The *Constellation®* Vision System is designed with a modular approach that allows the system to be highly configurable to meet the needs of many users. The system is designed around the Table Top where the accessories listed below can be added for expanded functionality.

- Table Top
- Base
- Laser Module
- Auxiliary Illuminator
- Tray Arm Assembly (includes ballast and support column)

The Table Top can operate as a standalone unit (Configuration 1), and is also the primary user interface that operates and controls the add-on accessories. All add-on accessories attach to the Base therefore, at a minimum, the Base must be installed prior to any system level customization. The table below shows the nine possible configurations for the *Constellation®* Vision System. Part numbers and ordering information is located in Section Six of this manual.

TABLE 1-1 SYSTEM CONFIGURATIONS

| Configuration | Table Top | Base | Tray Arm Assy | Laser Module | Auxiliary Illuminator |
|---------------|-----------|------|---------------|--------------|-----------------------|
| 1 | x | | | | |
| 2 | x | x | | | |
| 3 | x | x | x | | |
| 4 | x | x | x | x | |
| 5 | x | x | x | | x |
| 6 | x | x | x | x | x |
| 7 | x | x | | x | |
| 8 | x | x | | | x |
| 9 | x | x | | x | x |

TABLE 1-2 CONSTELLATION® VISION SYSTEM SPECIFICATIONS

| | | |
|--|-----------------------------------|--|
| <u>TABLETOP</u> Dimensions (length x width x height): 51 cm (20 in) x 48 cm (19 in) x 61 cm (24 in) Weight: 61 kg (135 lb) | | <u>PERFORMANCE SPECIFICATIONS</u> |
| <u>BASE</u> Dimensions: 74 cm (29 in) x 74 cm (29 in) x 97 cm (38 in) Weight: Base (no add-ons): 52.12 kg (115 lb) Base with Illuminator: 58 kg (128 lb) Base with Illuminator and Laser: 64.5 kg (142.2 lb) | | PRESSURIZED INFUSION/IRRIGATION @SEA LEVEL: Range: 0 to 120 mmHg Accuracy: ±(2% of setpoint +5 mmHg) Flow Rate: 0 - 20 cc/min. for infusion (20 Ga) 0 - 60 cc/min. for irrigation Setpoint Transient: 500 ms maximum |
| <u>TRAYARM</u> Dimensions: Tray: 56 cm (22 in) x 36 cm (14 in) Arm Fully Extended: 127 cm (50 in) Support Column: 110 cm (43 in) x 13 cm (5 in) x 15 cm (6 in) Weight: Tray and Arm: 11.7 kg (25.8 lb) Support Column: 5.5 kg (12.3 lb) | | IOP CONTROLLED INFUSION: Setpoint Range: 0-120 mmHg Repeatability ¹ : ± 2 mmHg ² Setpoint Response Time: <500 ms (20 Ga) Transient Disturbance Response Time: <500 ms ³ Flow Range: 0-20 cc/min |
| <u>BALLAST</u> Dimensions: 35 cm (14 in) x 35 cm (14 in) x 5 cm (2 in) Weight: 25.5 kg (56.2 lb) | | 1 BSS® Irrigating Solution Dual chamber mode. 2 BSS® Irrigating Solution medium, 20 gauge high flow Cannula, steady state condition at rated flow range 3 Transient condition from no flow state to 10cc/min |
| Note: If a base other than the optional Alcon base is used, it must be able to hold up to 250 pounds. | | |
| ENVIRONMENTAL LIMITATIONS: | | ASPIRATION/SUCTION @SEA LEVEL: Standard & Reduced Pressure Range: 0-650 mmHg Vacuum Minimal Pressure Range: 0-600 mmHg Vacuum Pressure Accuracy: ±(2% of Setpoint +5 mmHg) Flow Range: Posterior Modalities: 0-20 cc/min Anterior Modalities: 0-60 cc/min Transient Response Time (Standard Pressure Range): From 0 to -400 mmHg @0 cc/min 10-90% Rise Time: 300 msec max 90-10% Fall Time: 300 msec max |
| IP CODE | Console: IPX0 Footswitch: IPX8 | VACUUM @ SEA LEVEL: Vitrectomy: 0 to 650 mmHg Fragmentation: 0 to 650 mmHg Extrusion: 0 to 650 mmHg Extraction: 0 to 650 mmHg Irrigation/Aspiration: 0 to 650 mmHg Phacoemulsification: 0 to 650 mmHg |
| ELECTRICAL REQUIREMENTS: The console accepts the following ranges or input commercial power voltages and frequencies and meets the leakage currents specified in IEC 60601-1. Protection against electrical shock is Class I. | | LOW PRESSURE AIR SOURCE (LPAS) @SEA LEVEL: Pressure Range: 0 – 120 mmHg at rated flow Pressure Accuracy: ±2% of setpoint +5 mmHg Flow Rate: 1.2 slpm minimum at 120 mmHg |
| 100-120 Vac 50/60 Hz 12 A max. 220-240 Vac 50/60 Hz 6 A max. | | VITRECTOMY: Submodes: 3D, Momentary, PropVac, VitWet Cut Rate: UltraVit® 7500 Probe: 100 to 7500 cpm UltraVit® 5000 Probe: 100 to 5000 cpm UltraVit® 2500 Probe: 100 to 2500 cpm |
| <u>FOOTSWITCH</u> | | DIATHERMY: Frequency: 1.5 Mhz ± 10%. Waveshape: Sinusoidal Output power: 10 Watts maximum at 100% setting with 75 ± 10% ohm non-inductive load Output voltage: 163 Vpp maximum at 100% setting without load Power range: 0 - 100% of maximum output power |
| DIMENSIONS (length x width x height): 43.2 cm (17 in) x 26 cm (10.25 in) x 14 cm (5.5 in) | | DIATHERMY ACCESSORIES (Rated Voltage): Single Use Bipolar Cables: 846 Vpp Reusable Bipolar Cables: 1200 Vpp All Brushes: 1410 Vpp All Forceps: 1110 Vpp |
| WEIGHT: 5.4 kg (12 pounds) | | |
| ENVIRONMENTAL: The footswitch construction is water tight in compliance with IEC 60601-1 and IEC 60601-2-2, subclause 44.6 aa. | | |
| ELECTRICAL: The footswitch is connected to the console via electrical cable. All power and communications enter/exit the footswitch from this cable. | | |

TABLE 1-2 CONSTELLATION® VISION SYSTEM SPECIFICATIONS...continued

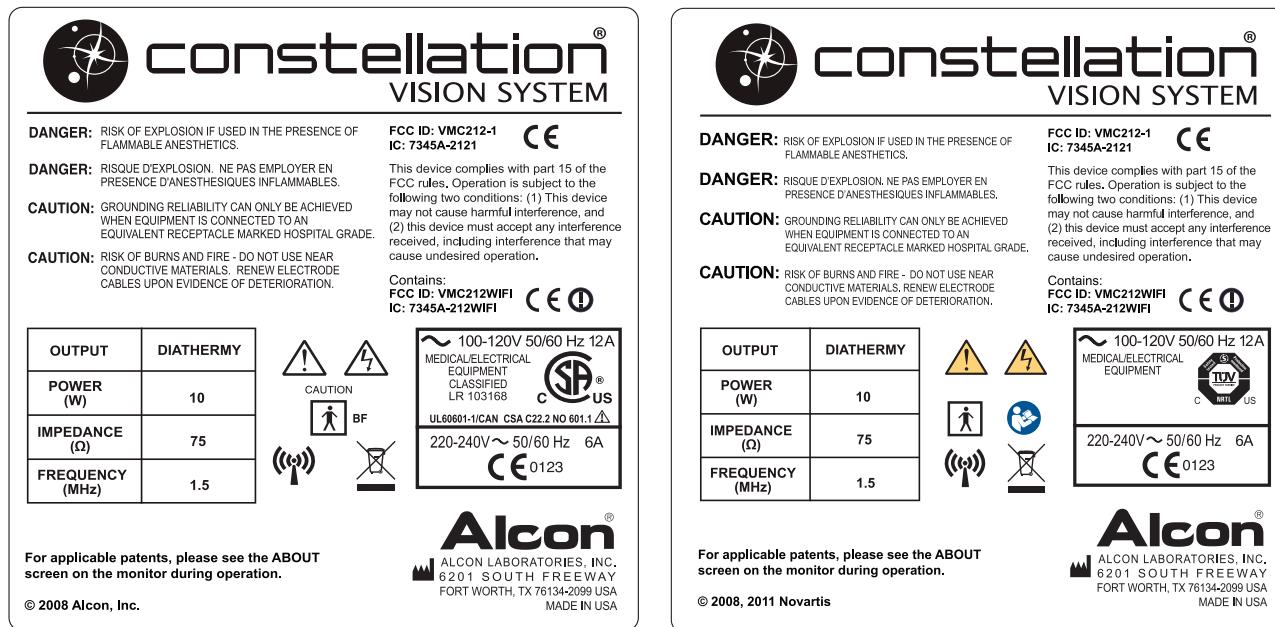
| | | | |
|--|--|-----------------------------|--|
| <u>PERFORMANCE SPECIFICATIONS...continued</u> | | | |
| ILLUMINATION: | | AUTO-STOPCOCK: | |
| Light Output through 20GA Fiber Probe: | 0-200 hrs: 16 ± 6 lumens at 115% set point ¹ 201-400 hrs: 16 ± 6 lumens at 115% set point ¹ | Response Time: | 0.5 seconds minimum |
| | | Pressure (Liquid): | 0-120 mmHg |
| Light Output through 23GA Fiber Probe: | 0-200 hrs: 23 ± 13 lumens at 115% set point ¹ 201-400 hrs: 23 ± 13 lumens at 115% set point ¹ | Rated Flow (Liquid): | 20 cc/min |
| Light Output through 25GA Fiber Probe: | 0-200 hrs: 23 ± 13 lumens at 115% set point ¹ 201-400 hrs: 23 ± 13 lumens at 115% set point ¹ | Pressure (LPAS): | 0-120 mmHg |
| | | Rated Flow (LPAS): | 1.2 slpm |
| PHACOEMULSIFICATION: | | PHACOEMULSIFICATION: | |
| | | Submodes: | Burst, Pulsed, Continuous |
| | | Tip Stroke @ 100%: | 3.5 ± 0.5 mils |
| | | Resonant Frequency: | 38.0 ± 2.5 KHz |
| | | Pulse Rate Range: | 0-100 pulses per second |
| | | Burst Length: | 2.5 sec – user adjustable |
| | | Burst Pulse durations: | 5 ms to 500 ms |
| OZi®: | | OZi®: | |
| | | Longitudinal Frequency: | 43.5 ± 3.0 KHz |
| | | Torsional Frequency: | 32.0 ± 2.0 KHz |
| | | Pulse Rate Range: | 0-100 pps |
| | | Longitudinal Burst Length: | 5 to 500 mS |
| | | Torsional Burst Length: | 2 to 500 mS |
| FRAGMENTATION: | | ANTERIOR VITRECTOMY: | |
| Submodes: | Linear, Fixed, Momentary | Submodes: | Wet, Dry |
| Tip Stroke @ 100%: | 3.1 ± 0.5 mils at 100% power | Cut Rate: | 0 to probe maximum |
| Resonant Frequency: | 43.5 ± 3.0 KHz | | |
| Pulse Rate Range: | 0 – 100 pps | | |
| SCISSORS: | | LASER (optional): | |
| Submodes: | Proportional, Multi-Cut | Treatment beam: | |
| Proportional Pressure: | 0-50 psi @sea level | Class: | 4 |
| Multi Cut Rate: | single cut to 450 cpm | Power: | 30 mW to 2 W (maximum) |
| | | Wavelength: | 532 nm |
| PROPORTIONAL AND CONTINUOUS REFLUX @SEA LEVEL: | | Aiming beam: | |
| Pressure Range: | 0 to 120 mmHg | Class: | 2 |
| Pressure Accuracy: | ±(2% of Setpoint +5 mmHg) | Power: | less than 1 mW |
| | | Wavelength: | 635 nm ± 5 nm |
| MICRO REFLUX: | | DOCTOR MEMORIES: | |
| Pressure Range: | 100 ± 50 mmHg ¹ | Storage Capacity: | No hard limit; advisory displayed when less than 15% of disk space is available. |
| Volume: | 15 ± 10 µL ¹ | | |
| ¹ measured with unoccluded 20 Ga <i>UltraVit™</i> probe and aspiration tubing | | | |
| VISCOUS FLUID CONTROL: | | TIMER: | |
| Submodes: | Inject, Extract | Range: | 0 to 99:99:99 |
| Injection Pressure: | 0 to 551.6 KPascal (0 to 80 psi) 0 to 482.7 KPascal @ Reduced (0 to 70 psi) | Resolution: | 1 s |
| Extract Vacuum at Sea Level: | 0 to 650 mmHg | REMOTE CONTROL: | |
| | | Method: | Infrared |
| | | Channels: | 4 |
| AUTO-GAS FILLING (AGF): | | | |
| Maximum Gas Pressure: | 10 psig | | |
| Fill Purity: | 97.1% gas concentration (minimum) | | |

TABLE 1-3 TERMS AND ABBREVIATIONS

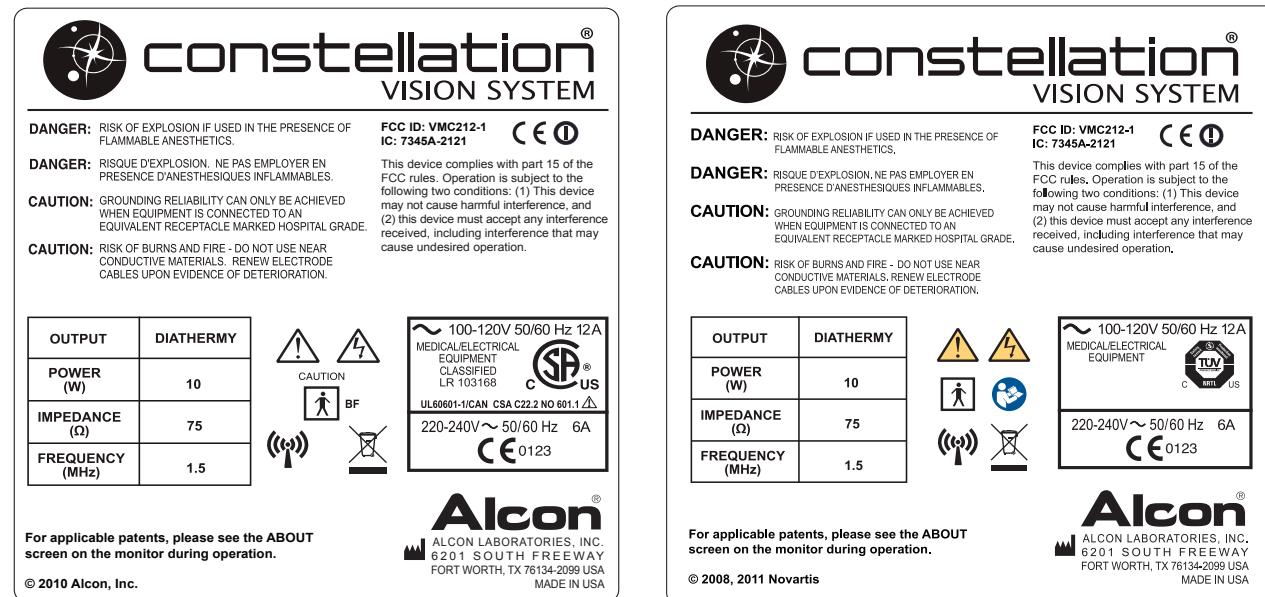
| Term or Abbreviation | Description |
|---|--|
| ACMI connector | The type of connector used on fiber optic probes. |
| AGF | Auto-Gas Filling |
| BSS PLUS® Intraocular Irrigating Solution | Sterile intraocular irrigating solution enriched with bicarbonate, dextrose, and glutathione. |
| cc/min | A unit of flow. |
| CE | A mandatory conformity mark on many products placed on the single market in the European Economic Area (EEA) |
| cmH ₂ O | Centimeters of water. A unit of pressure. |
| cpm | Cuts Per Minute |
| CSA | Mark to indicate that a product, process or service has been tested to a Canadian or U.S. standard and it meets the requirements of an applicable CSA standard or another recognized document used as a basis for certification. |
| Detent | A discrete footpedal position at which more force is required to depress the footpedal to the next position. |
| Diathermy | The production of heat in body tissues by electric current for therapeutic purposes. |
| Extrusion | A mode where vacuum is available to remove fluid/matter. |
| F/A/X | Fluid Air Exchange |
| Frag | Fragmentation |
| GA | Gauge |
| Global Function | A function whose status and controls are independent of the current footpedal position and surgery mode. |
| I/A | Irrigation/Aspiration |
| I/O | Input/Output |
| IOP | Intraocular Pressure |
| IEC | International Electromechanical Commission |
| ISO | International Standards Organization |
| IPX0/8 | International Protection code - Solid objects X (not specified) water 8/0 (continuous immersion/no test required) |
| IV | Intravenous |
| LCD | Liquid Crystal Display |
| mmHg | Millimeter of Mercury. A unit of vacuum and pressure. |
| Monolith | System configuration in which the Constellation® tabletop and base are paired together. |
| N/A | Not Applicable |
| PEL | Patient Eye Level. A difference in height between the cassette and the patient eye level. |
| PIN | Personal Identification Number |
| psi | Pressure per Square Inch. A unit of pressure. |
| pps | Pulses Per Second |
| RS-232 | A standard for serial binary data signals commonly used in computer serial ports. |
| slpm | Standard Liters Per Minute |
| Type BF | A classification for devices that have conductive contact with the patient, or have applied parts that are fixed in medium or long term contact with the patient |
| U/S | Ultrasound |
| USB | Universal Serial Bus |
| VFC | Viscous Fluid Control |
| VGA | Video Graphics Array |
| Vit | Vitrectomy. Extraction of the vitreous from the vitreous cavity. |

LABELING

Labels (including silk-screened labels) and icons may vary according to the date of manufacture of your system. To determine which label and icon version shown in Figures 1-2 and 1-3 apply to your system, compare the figures with the labels on your system and make the appropriate selection.



These labels applicable to Table Top # 8065751817 only.



58-120 Psi
400-825 kPa



15-30 Psi
103-107 kPa

Figure 1-2

LABELS USED ON THE CONSTELLATION® VISION SYSTEM -
Labels used on the system console are identified and illustrated here for reference only.

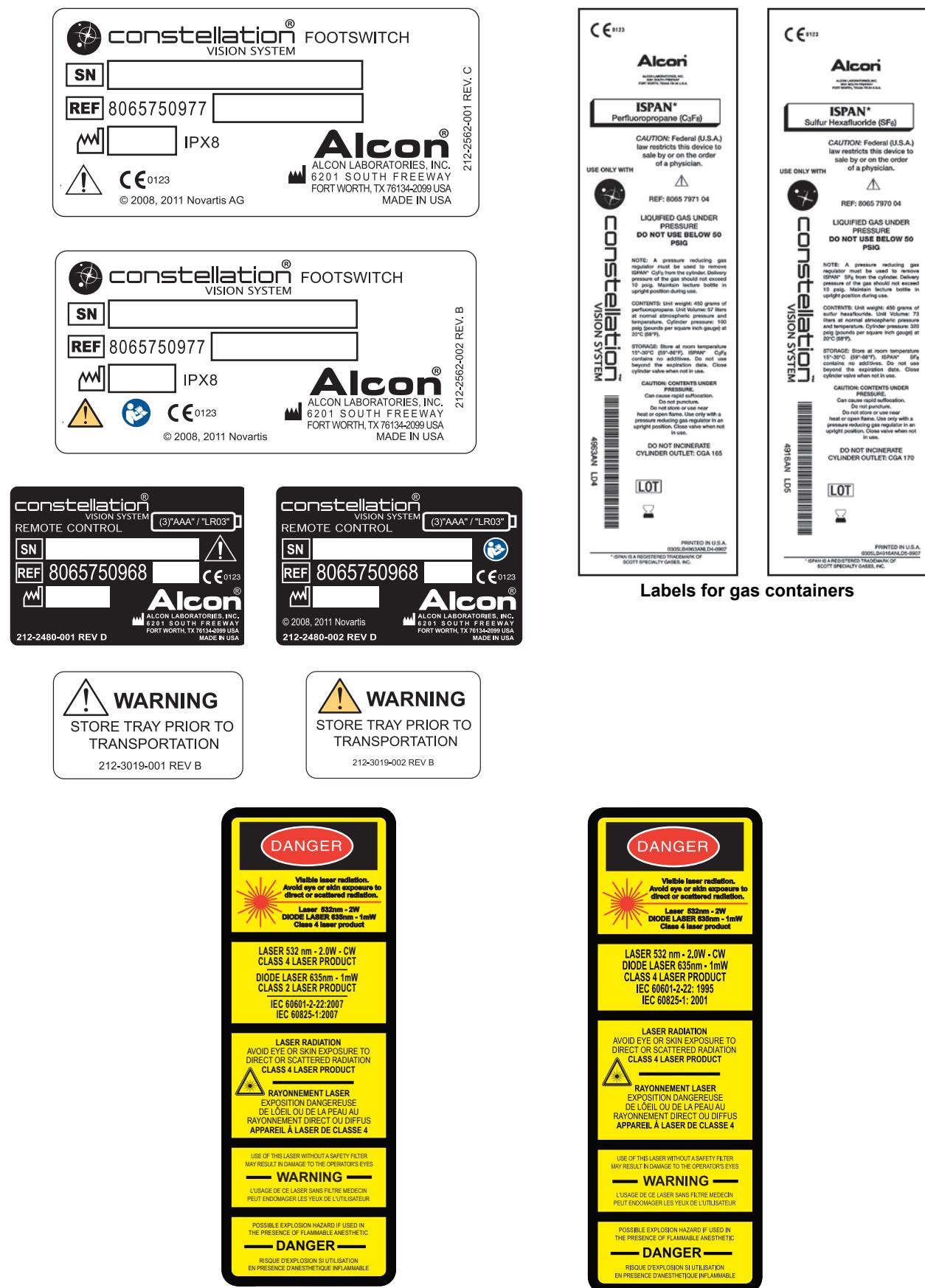


Figure 1-2 Continued from previous page.

| | | | | | |
|---|-----------------------------|---|---|---|-------------------------------|
|  | Extrusion |  | Auto Gas Filling (AGF) |  | I/O Data |
|  | Forceps |  | Alternating Current |  | Key Switch |
|  | Fragmentation |  | CE mark to RTTE directive |  | Laser Connection |
|  | Irrigation/Aspiration |  | CE mark to MD directive |  | Laser Emergency Stop Switch |
|  | Laser |  | OSHA recognized NRTL, CSA mark, providing electrical safety certification to North American requirements for medical devices. |  | Laser Port 1 |
|  | Phaco |  | OSHA recognized NRTL, TÜV SÜD America mark, providing electrical safety certification to North American requirements for medical devices. |  | Tethered Laser |
|  | Scissors |  | Coagulation Connector |  | Manufacturer |
|  | Viscous Fluid Control (VFC) |  | Connection Indicator |  | Multi-Function Port |
|  | Vitrectomy |  | Dangerous Voltage |  | Network Connection |
|  | Expand Window |  | Dangerous Voltage (black symbol with yellow background) |  | Non-ionizing Radiation |
|  | Help Video |  | Dr. Filter |  | Off |
|  | Modify |  | Eject |  | On |
|  | Power |  | Equipotentiality |  | Opens Operator's Manual |
|  | Save |  | Follow Instructions for Use (white figure with blue background) |  | Ready |
|  | AC In |  | Footswitch |  | Remote Door Lamp Laser Status |
|  | AC Out |  | Forceps |  | Remote Interlock |
|  | Aiming Beam |  | Hot |  | Scissors Connector |
|  | Air Pressure Input |  | Caution: Consult accompanying documents |  | Serial In/Out |
| | |  | General Warning (black symbol with yellow background) |  | Standby State |
| | |  | Illuminator |  | System Fault |
| | | | |  | System Information |
| | | | |  | Type BF Equipment |

Figure 1-3 ICONS USED WITH THE CONSTELLATION® VISION SYSTEM - Icons used with the system console are identified and illustrated here for reference only.

| | |
|---|----------------------------------|
|  | U/S Handpiece Connector |
|  | USB Connector |
|  | Use appropriate take-back system |
|  | Video Recorder Control |
|  | Viscous Fluid Control Connector |
|  | VGA Out |
|  | Video In |
|  | Video Out |
|  | Vitreous Cutter Connection |

Figure 1-3 Continued from previous page.

System Installation

In the USA contact the Alcon Technical Services Department for uncrating and installation at (800) 832-7827. Outside the USA contact your local Alcon affiliate.

Source Pressure Requirements (Air or N₂)

The *Constellation®* Vision System is designed to operate using clean filtered air or GN2 with different levels of source pressure. The system operates automatically with pressures of 58 (4 bar) to 120 psi (8.3 bar). **NOTES: Between 4 bar and 5 bar, vacuum performance is reduced. Between 4 bar and 5.5 bar, VFC inject performance is reduced.**

Accessory Equipment

Accessory equipment connected to or used with this equipment must be certified according to the respective IEC Standard (e.g., IEC 60601-1 for medical equipment). The *Constellation®* Vision System is shipped with English and metric fittings compliant with EN ISO 5359. Anyone connecting additional equipment or otherwise causing a different system configuration than provided by Alcon is responsible for continued compliance to the requirements of System Standard IEC 60601-1-1 and EN ISO 5359. If in doubt, consult the Technical Services department or your local Alcon representative.

WARNING!

Any non-medical equipment (i.e., VCR, monitor, MP3 player, etc.) must be placed outside the patient environment (at least 1.5 meters away from patient).

Environmental Issues

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

User Information - Environmental Considerations

The equipment that you have purchased requires the use of natural resources for its production and operation. This equipment may also contain hazardous substances which could have a potential effect on the environment and human health if disposed of improperly.

In order to avoid the entry of any such substances into our environment, and to promote natural resource conservation, please install, maintain, and operate the equipment in accordance with the instructions. Information on the location of hazardous substances, resource consumption and emissions of the equipment can be found throughout this Operator's Manual. Please use the appropriate take-back systems. Such take-back systems reuse or recycle many of the materials in your end-of-life equipment in a beneficial way. Please contact your local Alcon office for assistance in take-back options through Alcon or other providers.



Pb

The crossed-bin symbol located on this equipment reminds you to use take-back systems, while also emphasizing the requirement to collect waste equipment separately, and not dispose of it as unsorted municipal waste. The Pb notation, if present, indicates that the labeled device contains greater than 0.004% lead.

If you need more information on the collection, reuse or recycle systems available to you, please contact your local or regional waste administration, or contact your local Alcon office for more information.

Table 1-4 Information on the Location of Hazardous Substances in the Constellation® Vision System - The Constellation® Vision System contains hazardous substances which could have potential effect on the environment and human health if disposed of improperly.

| Material Location | Hazardous Substances Contained |
|--------------------------------------|--------------------------------------|
| Printed Circuit Board Assembly | Lead, Polybrominated Biphenyls (PBB) |
| Other Electrical / Electronic Device | Lead, Polybrominated Biphenyls (PBB) |
| Cable Assembly | Lead |
| Power Supply | Lead, Polybrominated Biphenyls (PBB) |
| Host PC Module | Lead, Polybrominated Biphenyls (PBB) |
| Liquid Crystal Display | Lead |
| Battery | Lithium, Zn/MnO ₂ |
| Remote Control | Lead |
| Fluidics Assembly | Lead |
| Pneumatic Assembly | Lead |

Universal Precautions

Universal precautions shall be observed by all people who come in contact with the instrument and/or accessories to help prevent their exposure to blood-borne pathogens and/or other potentially infectious materials. In any circumstance, wherein the exact status of blood or body fluids/tissues encountered are unknown, it shall be uniformly considered potentially infectious and handled in accordance with OSHA guidelines.

EMC Statement

It is important to install and use the equipment in accordance with the instructions in order to prevent harmful interference with other devices in the vicinity. If this equipment causes harmful interference to other devices (determined by turning the equipment off and on), the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the other device(s).

- Increase the distance between the equipment.
- Connect this equipment into an outlet on a circuit different from that to which the other device(s) is connected.
- Consult the manufacturer or your Alcon representative for help.

Table 1-5 Guidance and Manufacturer's Declaration - Electromagnetic Emissions -
The Constellation® Vision System is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

| Emissions Test | Compliance | Electromagnetic Environment-Guidance |
|---|------------|--|
| RF emissions CISPR 11 | Group 1 | The Constellation® Vision System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class A | Based on extensive field experience the Constellation® Vision System is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | The EMC Statement provides guidance on steps to take in case of electromagnetic interference. |
| Voltage fluctuations/ Flicker emissions IEC 61000-3-3 | Complies | |

Table 1-6 Guidance and Manufacturer's Declaration - Electromagnetic Immunity -
The Constellation® Vision System is intended for use in the electromagnetic environment specified below. The customer or the user of the Constellation® Vision System should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment-Guidance |
|---|---|---|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | <ul style="list-style-type: none"> • ± 6 kV contact • ± 8 kV air | <ul style="list-style-type: none"> • ± 6 kV contact • ± 8 kV air | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | <ul style="list-style-type: none"> • ± 2 kV for power supply lines • ± 1 kV for input/output lines | <ul style="list-style-type: none"> • ± 2 kV for power supply lines • ± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. To avoid laser stoppage due to fast transients avoid powering the Constellation® Vision System on the same branch circuit with sources that can generate fast transients (inductive switching; e.g., high current motors). |
| Surge IEC 61000-4-5 | <ul style="list-style-type: none"> • ± 1 kV differential mode • ± 2 kV common mode | <ul style="list-style-type: none"> • ± 1 kV differential mode • ± 2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. To avoid laser stoppage due to power-line surges consider powering the Constellation® Vision System through branch circuit that has surge suppressor for protection against lightning surges (e.g., at power panel to surgical/office suite). |
| Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11 | <ul style="list-style-type: none"> • $<5\%$ U_T ($>95\%$ dip in U_T) for 0.5 cycle • 40% U_T (60% dip in U_T) for 5 cycles • 70% (30% dip in U_T) for 25 cycles • $<5\%$ ($>95\%$ dip in U_T) for 5 sec | <ul style="list-style-type: none"> • $<5\%$ U_T ($>95\%$ dip in U_T) for 0.5 cycle • 40% U_T (60% dip in U_T) for 5 cycles • 70% (30% dip in U_T) for 25 cycles • $<5\%$ ($>95\%$ dip in U_T) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the uses of the Constellation® Vision System require continued operation during power mains interruptions, it is recommended that the Constellation® Vision System be powered from an uninterruptible power supply with a minimum rating of 1200VA. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the Constellation® Vision System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency to the transmitter. |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3V/m | <p>Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating to the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strength from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with following symbol.</p>  |

Note: U_T is the a.c. mains voltage prior to application of the test level.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Constellation® Vision System is used exceeds the applicable RF compliance level above, the Constellation® Vision System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Constellation® Vision System.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 1-7 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Constellation® Vision System -
The Constellation® Vision System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Constellation® Vision System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Constellation® Vision System as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter (W) | Separation distance according to frequency of transmitter (m) | | |
|---|---|--|---|
| | 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rates at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 - At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Equipment contains radio transmitters:

Radio Frequency Identification (RFID) device

- Frequency or frequency band of transmission: 13.56 MHz
- Type and frequency characteristics of the modulation: ASK
- The Effective Radiated Power (ERP): -119 dBm

Wireless LAN device (Compact USB WiFi Adapter WLI-UC-GNM)

- Frequency or frequency band of transmission: 2.412 – 2.462 GHz
- Type and frequency characteristics of the modulation: DSSS, OFDM, SISO
- The Effective Radiated Power (ERP): 20.55 dBm for USA & Canada

USA – Federal Communications Commission (FCC) Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

CAUTION

Change or modifications made to this equipment not expressly approved by Alcon may void the FCC authorization to operate this equipment.

FCC Radiation Exposure Statement

CAUTION

To ensure that the radio transmitter complies with current FCC regulations limiting both maximum output RF power and human exposure to radio frequency radiation, a separate distance of at least 20 cm must be maintained between the unit's antenna and the body of the user and any nearby persons at all times, and unit's antenna must not be co-located or operating in conjunction with any other antenna or transmitter.

The availability of some specific channels and/or operational frequency bands are country dependent and are firmware programmed at the factory to match the intended destination. This firmware setting is not accessible by the end user.

Canada – Industry of Canada (IC) Compliance Statement

This device complies with Industry Canada Radio Standards Specification RSS-210. Operation is subject to the following two conditions:

1. This device may not cause harmful interference
2. This device must accept any interference, including interference that may cause undesired operation of the device.

This ISM device complies with Canadian ICES-001.

Cet appareil ISM est conforme à la norme NMB-001 du Canada.

Industry of Canada (IC) Radiation Exposure Statement

CAUTION

This device complies with the RF exposure limits set forth a uncontrolled environment. This device should be installed and operated with minimum 20 cm between the unit's antenna and the body of the user. To maintain compliance with Canada RF exposure compliance requirements, please follow operation instruction as documented in this manual.

This transmitter must not be co-located or operating in conjunction with another antenna or transmitter.

Antenna Notices

This device has been designed to operate with the antenna having a maximum gain of 5 dBi. Antenna having a gain greater than 5 dBi is strictly prohibited for use with this device. The required antenna impedance is 50 ohms.

To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (EIRP) is not more than that required for successful communication.

Exposure of Humans to RF Fields

This device complies with the RF exposure limits for humans as called out in RSS-102.

Europe – R&TTE Directive 99/5/EC

This device complies with the requirements of the Council Directive 99/5/EC (R&TTE).

CAUTION

The radio equipment is intended to be used in all EU and AFTA countries. Outdoor use may be restricted to certain frequencies and/or may require a license for operation. Contact local Authority for procedure to follow.

Note: Combinations of power levels and antennas resulting in a radiated power of above 100mW equivalent isotropic radiated power (e.i.r.p) are considered as not compliant with the above mentioned directive and are not allowed for use within the European community and countries that have adopted the European R&TTE directive 1999/5/EC.

Certification and Compliance Marks for Compact USB WiFi Adapter WLI-UC-GNM, as specified in the Buffalo Technology labeling.

United States
FCC ID: FDI-09102085-0

Canada
IC ID: 6102A-032

EU
CE 0560 ①

ASIA PACIFIC



Complies with
IDA Standards
DA 103412

China
CMIIT ID: 2010DJ1757

KOREA
 인증번호 :
BUF-WLIUCGNM01

JAPAN

003WWA100448

TAIWAN

CCAI 10LP0720T3

WARNINGS AND CAUTIONS - GENERAL

Most of the warnings listed on the following pages are stated elsewhere in this manual; however, for easy reference they are repeated here. If additional information is required, please contact your local Alcon service representative, or the Technical Services Department. For locations outside the USA, please contact your local authorized Alcon Service/Sales office.

There are no user serviceable components inside the *Constellation®* Vision System console or footswitch. Refer all service issues to your factory-trained Alcon service engineer.

- Please contact Alcon for instrument setup and in-service training.
- Good clinical practice dictates the testing for adequate irrigation, aspiration flow, and operation as applicable for each handpiece prior to entering the eye.
- Initial setup instructions must be performed as outlined in this manual. If an error message is displayed on the front panel, refer to the Troubleshooting section of this Manual. If a problem persists, DO NOT PROCEED. Contact your local Alcon Surgical Service Representative.
- Do not use the *Constellation®* Vision System near flammable anesthetics.
- Provide at least two feet of clearance at the rear of the unit for fan intakes and exhausts. This ensures unrestricted air flow for adequate console cooling.
- A handle on the optional base is used for moving the instrument. The cart should be pulled, not pushed, over elevator and door thresholds.
- Use only Alcon-supplied A.C. power cords.

WARNINGS!

The *Constellation®* Vision System power cord is a medical grade power cord with the least leakage current per foot rating available. Extension of the power cord by hospital staff is not recommended. Unauthorized extension of the power cord could result in injury.

Do not use multiple portable socket (power strip) outlets with this system.

Store the tray arm prior to moving the instrument. See Section Three for instructions on placing the tray arm in the stored position.

Route the footswitch cable, power cord and other cables connected to the *Constellation®* Vision System to avoid tripping.

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth (Ground).

Modification of the equipment is NOT allowed without prior authorization from the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

Console isolation from mains is achieved through a two pole power switch. Turn OFF power switch or unplug the power cord from wall outlet to achieve isolation from mains.

WARNINGS AND CAUTIONS - PRESSURIZED INFUSION/IRRIGATION SOLUTIONS IN BAGS

When using the *Constellation®* Vision System in a pressurized infusion/irrigation mode, or with IOP Control feature enabled, users need to take precautions to NOT use *BSS®* irrigating solution or other infusion/irrigation mediums from pliable, collapsible containers (i.e. bags). The *Constellation®* system, when used in these pressurized modes, forces pressure into the infusion/irrigation container in order to force the solution out of the container and into the cassette. The pressure employed by the *Constellation®* system may cause some infusion/irrigation bags to rupture and cause disruption of the surgical procedures. Only glass containers should be used with the *Constellation®* Vision System when employing modalities of pressurized infusion/irrigation.

WARNINGS AND CAUTIONS - PATIENT EYE LEVEL/INFUSION PRESSURE

Patient eye level relative to the cassette can affect the infusion pressure being delivered to the eye. Be sure to enter the Patient Eye Level Offset to ensure that the displayed console readings reflect the true pressure being delivered to the eye.

WARNINGS AND CAUTIONS - PROBES AND HANDPIECES***WARNING!***

If in the medical opinion of the physician a patient with a prion related disease undergoes a high risk procedure, the instrument should be destroyed or be processed according to local requirements.

Vitreous Probes

Do not operate vitreous probes in air. This could result in performance degradation and/or potential hazard.

Ultrasonic (U/S) Handpieces

The *OZil®* torsional and high performance U/S handpieces are surgical instruments and must be handled with care. The handpiece tip should not touch any solid object while in operation. Immediately following surgery the handpiece must be thoroughly cleaned. Be sure the cord plug is completely dry before connecting it to console. For cleaning and sterilization procedures, see the Directions for Use (DFU) supplied with the handpiece.

During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.

If proper cleaning procedures are not performed immediately after each surgical procedure, tissue debris and salts from irrigating solution may collect. This could permanently damage the handpiece and could jeopardize cleanliness and/or create biohazard conditions for the patient. Remove all debris prior to autoclaving handpiece.

The *OZil®* torsional and U/S handpieces must be at room temperature just before use. Allow the handpiece to air cool for at least 15 minutes after autoclaving; never immerse the handpiece in liquid when hot. Power loss may occur if handpiece tip is not securely tightened into Fragmentation and Phaco handpieces.

CAUTION

Never ultrasonically clean the Fragmentation, *OZil®* torsional and ultrasonic handpieces; irreparable damage will result.

Ensure that test chamber is filled with *BSS®* sterile irrigating solution before tuning the *OZil®* torsional and U/S handpieces. Tuning a handpiece dry may result in premature tip failure and breakage.

Do not test or operate the *OZil®* torsional and U/S handpieces unless the tip is immersed in *BSS®* sterile irrigating solution or distilled water or is in surgical use. Irreparable damage to the handpiece and tip can result if run dry.

WARNINGS!

Use of the *OZi*® torsional and U/S handpiece in the absence of irrigation flow and/or in the presence of reduced or lost aspiration flow can cause excessive heating and potential corneal and/or scleral burns.

Use of the Fragmentation handpiece in the absence of aspiration flow can cause excessive heating and potential scleral burns.

Use of an ultrasonic handpiece other than the *OZi*® torsional or U/S, or use of a handpiece repaired without Alcon authorization, is not permitted, and may result in patient injury, including potential shock hazard to patient and/or operator.

Prior to sterilization, the *OZi*® torsional and U/S handpieces should always have the connector end cap secured and placed in the sterilization tray. This will prevent damage to the connectors and handpieces during handling, and especially during autoclaving.

Quenching a hot handpiece in water can cause damage and will void warranty.

Be sure handpiece is completely dry before connecting it to console. Damage to handpiece and console may result if plugged in when wet.

The U/S tips supplied in the *Constellation*® Vision System packs are only to be used on the *OZi*® torsional or U/S handpieces. Each U/S tip is intended to be used only once per case, and then disposed of according to local governing ordinances.

Good clinical practice dictates testing for adequate irrigation, aspiration flow, reflux, and operation as applicable for each handpiece prior to entering eye.

Appropriate use of *Constellation*® Vision System parameters and accessories is important for successful procedures. Use of low vacuum limits, low flow rates, low irrigation pressure, high power settings, extended power usage, power usage during occlusion conditions (beeping tones), failure to sufficiently aspirate viscoelastic prior to using power, excessively tight incisions, and combinations of the above actions may result in significant temperature increases at incision site and inside the eye, and lead to severe thermal eye tissue damage.

Directing energy toward non-lens material, such as iris or capsule, may cause mechanical and/or thermal tissue damage.

WARNINGS AND CAUTIONS - HANDPIECE TIPS

Scissors, frag, and phaco handpiece tips must be fully tightened to their handpieces. If not secured properly, the handpieces may not operate correctly. Ensure, however, that tips are not so tight that they cannot be removed after use. Use of a tool other than tip wrenches supplied by Alcon may cause damage to the tip and/or handpiece.

WARNING!

Use 0.9 mm tips with 0.9 mm infusion sleeves. Use 1.1 mm tips with 1.1 mm infusion sleeves. Mismatch of consumable components and use of settings not specially adjusted for a particular combination of consumable components may create a patient hazard.

Poor clinical performance will result if tip is not secured tightly to the handpiece.

WARNINGS AND CAUTIONS - DIATHERMY FUNCTION

To ensure safe operation of the Diathermy function, use only Alcon cables and accessories. Diathermy performance can be guaranteed only when using Alcon Surgical components or Alcon-endorsed components. Cables should always be positioned in such a way that contact with the patient is prevented.

See Figures 1-4 through 1-6 for diathermy power specifications.

WARNING!

- **Do not use the diathermy function on patients with pacemakers or implanted defibrillatory devices. If electrosurgery is used on patients with implanted cardiac pacemakers or defibrillatory devices or pacemaker electrodes, be aware that irreparable damage to the pacemaker or defibrillatory device and its function may occur and lead to ventricular fibrillation. Please check with the pacemaker or defibrillatory device manufacturers for their recommendations.**
- **Failure of the HF surgical equipment (diathermy circuitry) could result in an unintended increase of output power. In this event the following advisory is displayed: "Handpiece power is too high. Release footswitch button/treadle and try again."**

Listed below are general precautions to be followed when using the Diathermy function:

- To ensure safe operation of the Diathermy function, only approved cables and accessories must be used (See your Alcon representative). Diathermy performance can be guaranteed only when using Alcon components or Alcon-endorsed components.
- To reduce the risk of accidental burns, caution should always be taken when operating high-frequency surgical equipment.
- Interference produced by the operation of high-frequency surgical equipment may adversely influence the operation of other electronic equipment.
- Accessories should be checked regularly; electrode cables should particularly be checked for possible damage to the insulation.
- The lowest power level in Diathermy step should always be selected for the intended purpose.
- Skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze.
- When HF (high frequency) surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended.
- In all cases, monitoring systems incorporating high frequency current-limiting devices are recommended.
- The cables to the surgical electrodes should be positioned in such a way that contact with the patient or other leads is avoided.
- Temporarily unused active electrodes should be stored so that they are isolated from the patient.
- The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.

- Non-flammable agents should be used for cleaning and disinfection wherever possible.
- Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF surgery. Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in normal use of the HF surgical equipment.
- Accessories of the Diathermy function should have a rated voltage equal to or greater than the maximum diathermy output voltage.

WARNINGS AND CAUTIONS - ILLUMINATOR FUNCTION

WARNINGS!

The illuminator bulbs become extremely hot. Never handle a bulb until it has cooled considerably from its operating temperature. Do not touch bulb directly with fingers at any time.

The bulb of the xenon lamp is under constant high pressure. There is a risk it may burst with explosive force if knocked or damaged. Protective measures:

- Keep the lamp in its protective sleeve at all times during installation
- If you are handling the lamp without its protective sleeve, always wear safety goggles, a face mask, gloves with wrist protectors and a breast protector.

If the optional illuminator is not installed inside the *Constellation®* system base, be sure that your surgical set-up includes a back-up source for illumination.

Use of controls or adjustments, or performances of procedures other than those specified herein may result in hazardous light exposure.

To minimize hazardous light exposure, operate light source at lowest intensity setting consistent with adequate visibility of the surgical area.

Light output from a new lamp may greatly exceed the output from an old lamp. Adjust to lower settings after installing a new lamp.

Do not use this light source in the presence of flammable substances.

The fiber optic endoilluminator probe connector and receptacle may be hot.

Before each use, visually inspect the outer surface of the distal tip of the fiber optic endoilluminator probe that will be inserted into the patient to ensure that there are no unintended foreign materials, rough surfaces, sharp edges, or protrusions, that may cause patient injury.

Potentially hazardous radiated light is transmitted from the fiber optic endoilluminator probe. Refer to Retina Risk Factors to Consider During Operation of the *Constellation®* Illuminator in this section of the manual for advice on how to minimize the effects of the light intensity used.

Avoid operation of any fiber in air on consoles capable of illumination levels and settings higher than 10 lumens. This may result in fiber probe deformation and/or high surface temperatures that may cause patient injury.

WARNINGS AND CAUTIONS - FOOTSWITCH

Never pick up or move the footswitch by holding the cable. Damage may result.

WARNING!

Route the footswitch cable properly to avoid tripping.

WARNINGS AND CAUTIONS - CASSETTE

Manually rotating the hub roller in the cassette well when power is on and a cassette is not installed can cause incorrect cassette loading and/or can cause injury to fingers.

WARNINGS!

All fluids aspirated during surgery should be treated as biohazards. Take appropriate precautions when handling instruments and lines in contact with aspirated fluids.

Drain bag volume should not exceed 500 ml "Max. Capacity." Exceeding this volume may result in a biohazardous condition.

WARNINGS AND CAUTIONS - CONSUMABLES

Do not use consumable packs beyond the expiration date stamped on the outer packaging. Sterile consumable medical devices should not be reused (Accreditation Manual for Hospitals, 1982); they are intended for single use only. Improper usage or assembly could result in a potential hazardous condition for the patient. Alcon assumes no responsibility for complications that may arise as a result of the reuse or improper usage of consumables.

WARNING!

Potential risk from reuse or reprocessing the following products labeled for single use include:

- **Bipolar Coagulation Instruments** - Thermal injury or electrical shock caused by a damaged bipolar instrument, and foreign particle introduction into the eye.
- **Fiber Optic Instruments** - Phototoxicity from inconsistent laser or illumination exposure caused by a damaged fiber or connector, reduced laser/illumination output, and foreign particle introduction into the eye.
- **Fluid Management Components** - Fluid path leaks or obstruction resulting in reduced fluidics performance, and foreign particle introduction into the eye.
- **Phacoemulsification Tips** - Reduced tip cutting performance, presence of tip burrs, fluid path obstruction, and foreign particle introduction into the eye.
- **Vitreous Cutting Instruments** - Reduced vitreous cutting performance, fluid path obstruction, and foreign particle introduction into the eye.

The equipment used in conjunction with Alcon *Constellation®* Vision System consumables constitutes a complete system. Use of consumables other than Alcon consumables may affect system performance and create potential hazards, and if it is determined to have contributed to the malfunction of the equipment under service contract, could result in the voidance of the contract and/or invoicing at prevailing hourly rates.

WARNING!

Attach only Alcon supplied consumables to console and cassette luer fittings. Do not connect consumables to the patient's intravenous connections.

In all cases, the instrument setup instructions contained in this manual, and all label instructions in the package, should be thoroughly understood prior to using any of the *Constellation®* Vision System Pack configurations.

Ensure that tubing is not occluded during any phase of operation.

Consumable Packs

If any item in a consumable pack is received in a defective condition, Alcon is to be notified immediately. Do not use any of the contents if the sterile package is damaged or the seal is broken in any way. Packs are identified by lot number that provides traceability and should be given to the Customer Service Department.

Phone Alcon Customer Service At:
(800) 862-5266 or
(817) 293-0450

Please Write To Alcon At:
Alcon
Attn: Product Complaints
6201 South Freeway
Fort Worth, TX 76134-2099

WARNINGS AND CAUTIONS - IOP (INTRAOCULAR PRESSURE)

The closed loop system that adjusts IOP cannot replace the standard of care in judging IOP intraoperatively. The surgeon must continue the common practice of informally judging IOP using the following:

- Finger palpation on the globe
- Tactile feedback of the surgical instruments (eye wall deformation with manipulation of instruments)
- Retinal vessel perfusion/pulsations
- Presence of corneal edema

If the surgeon believes the IOP (using the techniques above) is not responding to the system settings and is dangerously high, this may represent a system failure. The surgeon can do one or more of the following as they deem appropriate in this situation (with care to avoid sudden hypotony):

- Close the infusion stop-cock
- Pinch the infusion line
- Remove the infusion line from the sclerotomy

NOTE: To ensure proper IOP Compensation calibration, place infusion tubing and infusion canula on a sterile draped tray at mid-cassette level during the priming cycle.

WARNINGS AND CAUTIONS - LASERS

The footswitch, endoprobe, and LIO should be placed within 2 meters of the *Constellation®* Vision System.

WARNINGS!

There are potential hazards when inserting, steeply bending, or improperly securing the fiberoptic. Not following the recommendations of the manufacturer may lead to damage of the fiber or delivery system and/or harm to the patient or user.

Since the aiming beam passes down the same delivery system as the treatment beam, it provides a good method of checking the integrity of the delivery system. If the aiming beam spot is not present at the distal end of the delivery system, or its intensity is reduced or it looks diffused, this is a possible indication of a damaged or not properly working delivery system. If there is any doubt, contact Alcon Technical Services.

The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen should be avoided. Some materials - for example cotton wool when saturated with oxygen - may be ignited by the high temperatures produced in normal use of the laser equipment. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. There is also danger of ignition of endogenous gases.

Diathermy, Cautery, Coagulation

In the past, some of Alcon's products have referred to the feature "Cautery" or "Coagulation." The *Constellation®* Vision System and this operator's manual use the word "Diathermy" based on the following definitions:

- Diathermy - introducing an electric field into a body part to produce heat.
- Cautery - cutting and burning method associated with two hot wires passing a current between them; cutting away skin; halting bleeding.
- Coagulation - an isolated bipolar current supplied to conductors (e.g. forceps). Current passes between these electrodes, halting bleeding.

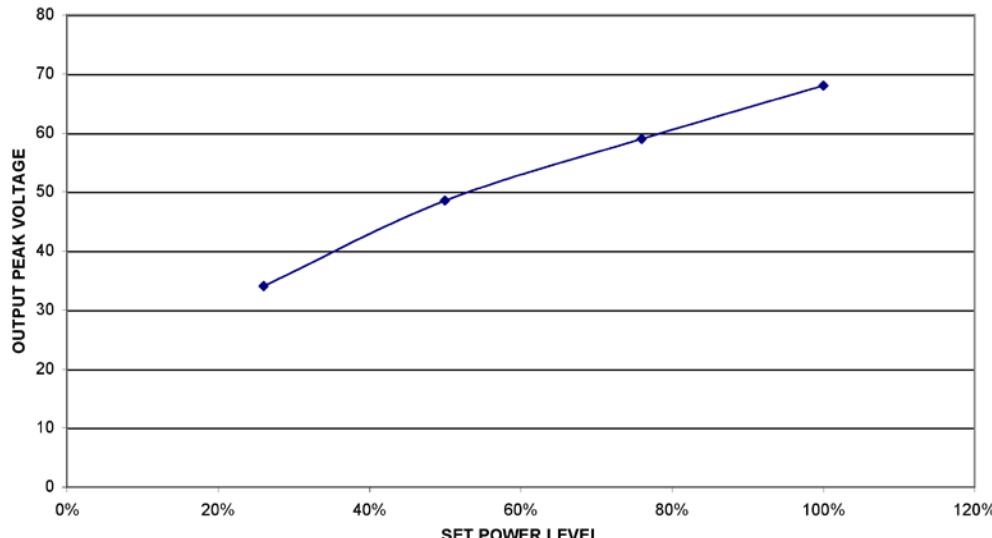


Figure 1-4 Diathermy Power Through 75 Ohm Load

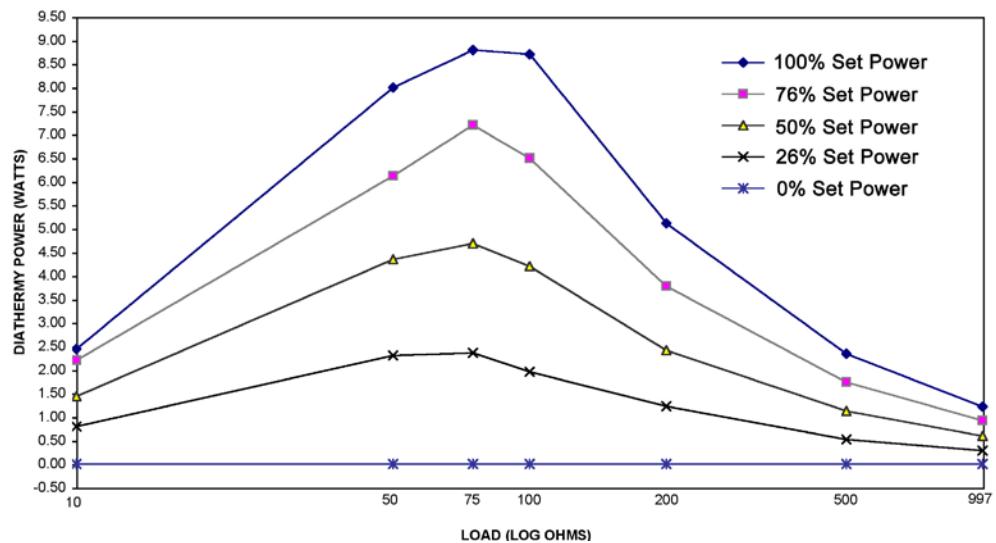


Figure 1-5 Diathermy Power vs. Load Impedance

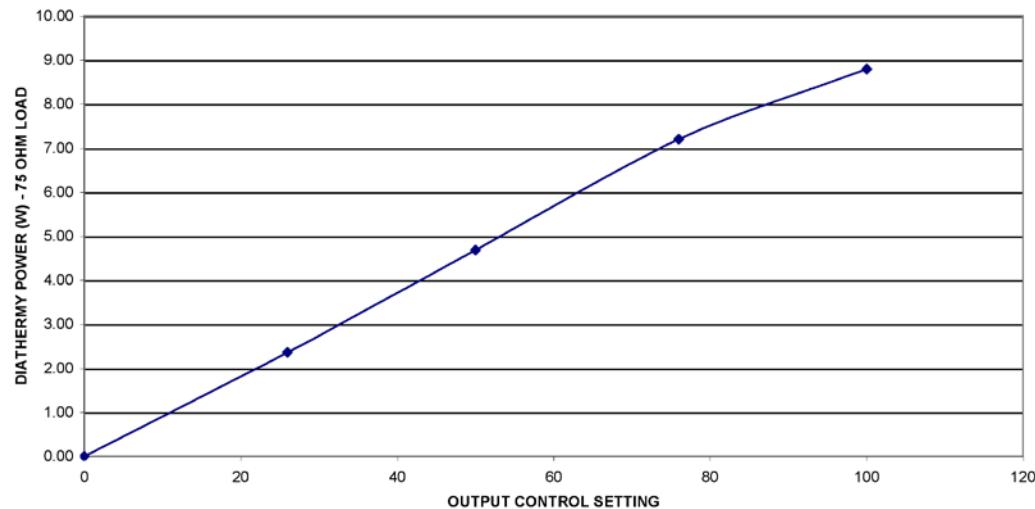


Figure 1-6 Diathermy Output Voltage vs. Output Control Setting

Note: Maximum output peak-to-peak voltage is about 140V without resistive load.

PRODUCT SERVICE

For product service, please contact Alcon's Technical Services Department at the number provided below.

Operators experiencing problems with the system should refer to the Operating Instructions and Troubleshooting sections of this manual. A problem which persists should be referred to the Alcon Technical Services Department or your local authorized service representative.

For optimum performance, it is the user's responsibility to schedule preventive maintenance service on the system and its accessories two times each year. Alcon's Field Service Engineers are trained and equipped to provide the highest quality of workmanship.

Safety performance should be verified by the user (e.g., qualified service personnel) at least twice a year. Ground resistance must be under 0.1 ohms. Leakage current must be under 500 μ A at 264 Vac or 300 μ A at 132 Vac.

To avoid unnecessary shipping, please contact your Alcon Technical Services Department prior to the return of any system or accessories. If return of the equipment is deemed necessary, a Return Material Authorization will be issued with appropriate shipping instructions.

Alcon Laboratories, Inc.
Technical Services Department
15800 Alton Parkway
Irvine, California 92618-3818
(949) 753-1393
(800) 832-7827

LIMITED WARRANTY

Alcon Laboratories, Inc., will repair or replace at its option, any system or accompanying accessories (excluding the optical fiber) found to be defective in material and/or workmanship for a period of one (1) year from the date of initial installation. If optional laser is included, the laser core module will be warranted three years from the date of initial installation. This warranty applies to the original purchaser of the system, when said system is properly installed, maintained, and operated in accordance with published instructions.

Alcon Laboratories shall not be obligated to provide services under this warranty for damage to or destruction of systems covered where such damage or destruction is (i) a result of or caused by fire or explosion of any origin, riot, civil commotion, aircraft, war, or any Act of God including, but not limited to lightning, windstorm, hail, flood, earthquake, or (ii) caused by customer's misuse or improper servicing of said systems.

The express warranty above is the sole warranty obligation of Alcon, and the remedy provided above is in lieu of any and all other remedies. There are no other agreements, guarantees, or warranties - oral or written, express or implied - including without limitation warranty of merchantability or fitness for a particular purpose. Alcon shall have no liability whatsoever for any incidental or consequential damages arising out of any defect, improper use, or unauthorized service or repair.

WARNING!

The disposables used in conjunction with Alcon instrument products constitute a complete surgical system. Use of disposables and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards. If it is determined that disposables or handpieces not manufactured by Alcon have contributed to the malfunction of the equipment during warranty period, service will be provided at prevailing hourly rates.

ILLUMINATOR PROFESSIONAL USER'S INFORMATION:

RETINA RISK FACTORS TO CONSIDER DURING OPERATION OF THE CONSTELLATION® ILLUMINATOR

Spectral Output

The *Constellation®* illuminator comes equipped with internally-integrated, non-selectable, UV/IR filtration. No removable filters are used in the *Constellation®* illuminator since the retinal hazard is maintained at the levels specified by ISO 15752-2005.

The *Constellation®* illuminator output spectrum complies with the requirements of ISO 15752-2005: "Ophthalmic Instruments - Endoilluminators - Fundamental Requirements and Test Methods for Optical Radiation Safety." The *Constellation®* illuminator does not rely on fiber optic endoilluminator probe absorption to comply with spectral output requirements of ISO 15752-2005. It delivers light at the fiber optic illuminator connector within the spectrum recommended by ISO 15752-2005.

Spectrally-Weighted Aphakic Irradiance

Aphakic irradiance for the *Constellation®* illuminator was determined using approved fiber optic endoilluminator probes approved for use with the *Constellation®* illuminator. The value for Spectrally-Weighted Aphakic Irradiance (SWAI) of the endoilluminator was determined with an effective 3 mm-diameter aperture at a distance of 5 mm in a plane perpendicular to the radiating fiber optic endoilluminator probe tip.

Output Limits

To avoid potentially unsafe operations of the *Constellation®* illuminator, the system will warn or prevent the user when certain thresholds are exceeded. The *Constellation®* illuminator limits output and aphakic weighted irradiance to stay within safe limits based on the type of fiber used. Using RFID, the type of fiber is detected by reading information from the RFID tag within the inserted fiber probe. Utilizing the fiber type information the *Constellation®* illuminator sets a series of limits on output. Four separate thresholds are used:

Damage Limit - The Damage Limit corresponds to the maximum output of the illuminator that any given RFID recognized fiber can be safely operated without risking damage to the probe while operation in air. When the intensity of the output of the *Constellation®* illuminator is increased by the user beyond the damage limit, a pop up message is displayed that warns the user "Further increasing the output level in air can damage fiber tips. Would you like to continue?" If the user presses the [Yes] button, the request (turning on illuminator, changing the set point while the illuminator is on, or changing procedures while the illuminator is on) will be granted. If the user presses the [No] button, the system state will be unchanged. No interactions with the illuminators are allowed while the advisory is being displayed

Soft Limit - The Soft Limit for any given RFID recognized fiber corresponds to a peak aphakic weighted irradiance of 100.98 mW/cm² for a nominal fiber optic endoilluminator probe at a distance of 5 mm from the exiting aperture. The *Constellation®* system display is scaled so that the level will display 100% at the soft limit. When the output intensity of the *Constellation®* illuminator is increased by the user beyond the soft limit, a pop up message is displayed which warns the user “Further increasing the output level will reduce exposure time by 35%. Would you like to continue?” If the user presses the [Yes] button, the request (turning on illuminator, changing the setpoint while the illuminator is on, or changing procedures while the illuminator is on) will be granted. If the user presses the [No] button, the system state will be unchanged. If the advisory was brought up as a result of a procedure change, the setpoint(s) that exceeded the limit will remain at the previous value. No interactions with the illuminators are allowed while the advisory is being displayed.

Hard Limit - The Hard Limit for any given RFID recognized fiber corresponds to a peak aphakic weighted irradiance of 115.85 mW/cm² for a nominal fiber optic endoilluminator probe at a distance of 5 mm from the exiting aperture. The displayed intensity percentage output of the *Constellation®* illuminator is scaled so that 115% corresponds the Hard Limit for that fiber. The user is not given the ability to exceed this limit.

Port Limits - To further avoid potentially unsafe operation, the *Constellation®* illuminator will prevent more than two illuminator ports from being turned on at the same time. If the user attempts to turn on a third port, a pop up message is displayed which warns the user “Only two illuminators can be turned on simultaneously.”

LASER PROFESSIONAL USER'S INFORMATION:

The following information is given to provide the operator with specific information regarding the *Constellation®* Vision System Laser ophthalmic laser.

Indications

The *Constellation®* Vision System Laser is indicated for use in photocoagulation of both anterior and posterior segments of the eye including:

- Retinal photocoagulation, panretinal photocoagulation, and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including:
 - Proliferative and nonproliferative retinopathy (including diabetic)
 - Choroidal neovascularization secondary to age-related macular degeneration (AMD)
 - Retinal tears and detachments
 - Macular edema
 - Retinopathy of prematurity;
 - Choroidal neovascularization;
 - Leaking microaneurysms.
- Iridotomy/iridectomy for treatment of Chronic/Primary Open Angle Glaucoma (COAG, POAG), Acute Angle Closure Glaucoma (AACG), and refractory glaucoma.
- Trabeculoplasty for treatment of Chronic/Primary Open Angle Glaucoma (COAG, POAG) and refractory glaucoma.
- And other laser treatments including:
 - Internal sclerostomy
 - Lattice degeneration
 - Central and branch retinal vein occlusion
 - Suturelysis
 - Vascular and pigmented skin lesions.

LASER SAFETY

General Safety Precautions (Refer to IEC 60825-1 or ANSI Z136.1)

- A laser safety officer should be appointed to supervise the installation and use of the system.
- Install an indicator light outside the laser room warning of instrument operation.
- Position all beam delivery devices (e.g. LIO, endo-probes) so that the laser beam is never directed toward a door, window, or reflective surface.
- Use non-reflective matte finish wall paint.
- Avoid covering laser room floor and walls with carpet or any other dust generating material. This will minimize the possibility of excess grime and dust on the instrument optics, and interference with equipment cooling.
- The instrument requires a minimum of 0.5 meter of open space on all sides for proper cooling ventilation; therefore, the system should be set flat, resting on the legs provided on the bottom of the console.
- Unauthorized use of this laser should be prevented by removing the On/Off key.
- Entrances to areas or protective enclosures containing Class 4 lasers should be posted with appropriate warning signs.
- Appropriate eye protection must be used in all hazard areas. Use eye protection with OD 4 or above at 532 nm.

Nominal Ocular Hazard Distance (NOHD)

| Accessory | Beam Divergence (NOHD) |
|------------------|----------------------------------|
| <i>LIO</i> | <i>0.024 radians (20 meters)</i> |
| <i>Endoprobe</i> | <i>0.23 radians (3 meters)</i> |

- A qualified technician must verify that the power plug used is properly grounded.
- The remote interlock connector should be connected to an emergency master disconnect interlock or to room/door/fixture interlocks. Please refer to figure 1-7.
- The laser footswitch, endoprobe, and LIO should be placed within 2 meters of the Constellation® Vision System Laser.

CAUTION

Before turning the instrument ON for the first time after receipt of the system, wait one hour for the components and optics to normalize to avoid possible condensation that may have occurred during shipping.

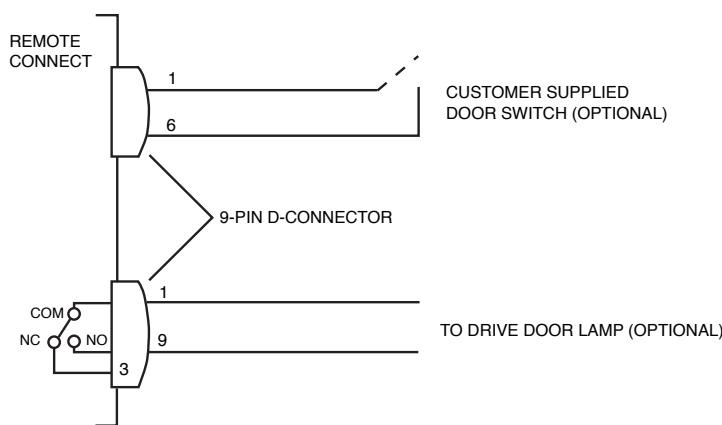


Figure 1-7 Remote Connector/Door Lamp Circuit Diagram

Laser Safety Features

The *Constellation®* Vision System Laser is designed for the highest degree of reliability and safety for both the operator and the patient. Any misuse of this laser system may be dangerous. Before using the laser system, the operator must be familiar with the commands and the operation of this type of instrument.

The *Constellation®* Vision System Laser is fitted with the following safety systems which must be understood by every operator:

- A protective housing covers the laser source so that no harmful laser radiation will be emitted. No part of this protective housing should be removed by the operator. The laser system must not be used if the protective housing has been damaged or removed.
- A remote connection (interlock) is located on the rear panel and permits the installation of an external switch. This switch can be installed on the laser room door and cuts off all laser emissions in case the door is opened during operation. There is also a connector linked to an internal relay to activate a door warning lamp if desired.
- A key switch controls the laser power supply. Laser operation is not possible if the key has been removed. Access to the key should be limited to authorized and knowledgeable personnel. The key should not be left on or near the instrument when not in use.
- During operation, laser status can be determined by visually checking the display to determine the laser mode: Standby or Ready.
- An emergency switch is mounted on the front panel. Pushing this switch will cut off all laser emissions (treatment and aiming beam) at any time. The switch must be pulled out to the initial position to restore power. The laser will always restart in Standby mode.
- Laser firing commands are microprocessor controlled and firings are prevented should any malfunction be detected in the instrument electronics. The instrument will only fire when all conditions are correct.
- Output power of the laser beam is continuously monitored and controlled. In case an unusual power condition is detected, firing stops and the treatment laser emission is cut off.

Effects

The laser beam is primarily absorbed by pigmented tissues within the eye. These primary pigments are hemoglobin/oxy-hemoglobin and melanin. In the case of macular treatment, xanthophyll pigment is involved. The surgeon controls the power, spot size, and exposure time of the delivered laser beam to the targeted tissue. It is the combination of these effects that results in the thermal action of the laser beam upon tissue. One or all of the adjustable parameters can be changed. However, in normal clinical practice, power is usually varied, and spot size and exposure time are preset as a function of the application.

The 532 nm green laser beam has similar absorption characteristics to the 577 nm dye yellow laser beam⁷. This means that the absorption effects of the 532 nm wavelength are considerably higher in hemoglobin and melanin, and less in xanthophyll. In all cases, it is necessary to perform titrations until the desired treatment results are obtained. The 532 wavelength also requires less power than that required with the argon laser to obtain similar results. Therefore, you should begin your titration levels with lower power than required for similar procedures with the argon laser.

WARNING!

Failure to titrate delivered energy may result in patient injury.

Use of this medical laser, as with any other instrument, requires training and experience to obtain maximum clinical performance. Titrating the dosage is recommended by initiating a lesion formation in an area of normal retina with intact pigment epithelium. Power and exposure duration should be varied incrementally until the desired lesion is produced.

WARNING!

If unsure which settings are required, select low power, short duration, and large spot size. Failure to do so may result in patient injury.

Delivery of Laser Energy

The laser beam is delivered to tissue via an endoprobe, illuminated endoprobe, aspirating endoprobe, or Laser Indirect Ophthalmoscope (LIO). Reaction to applied laser energy by the eye is a function of many variables.

The pigmentation of the eye, technique or procedure used, laser settings, and pre-existing condition of the eye, such as cataract, will have an effect on the selected laser parameters and the results obtained. Therefore, it is very important to consider all the existing clinical conditions and titrate until the desired results are obtained.

Always use minimal illumination while maintaining good visualization in order to reduce reflections and discomfort for the patient. Likewise, the aiming beam should be used at a minimum setting while maintaining proper targeting of the selected tissue. This will also minimize excessive reflections and scattering, particularly at smaller spot sizes.

Doctor Protection Filter

The *Constellation®* Vision System laser can only be fired when appropriate steps are taken to ensure that a doctor's filter is placed in the viewing device (e.g. surgical microscope, etc.). The *Constellation®* Vision System laser supports two types of doctor filters:

- Non-tethered with fixed filter in viewing path.
- Tethered with manual switch to place filters in and out of the viewing path.

The doctor protection filter must remain in the beam path during treatment, enabling the targeted tissue to be seen with complete protection for the operator. The filter has virtually no effect on visualization (colored** view only).

Rotation of the tethered filter with manual switch in or out of the beam path is accomplished by means of a lever located on the right side of the filter. Note that if the doctor protection filter is in the open position in endo modes, the laser will not fire and the message "Please Engage Dr. Filter" will appear. Rotate the filter lever clockwise until the doctor protection filter is in the beam path and the message clears. If using a non-tethered fixed filter, and the system is switched from Standby to Ready mode, the message "Verify appropriate Dr. Filters are installed in all viewing devices" appears and the user must verify before the laser can switch to Ready mode.

If two tethered filters are in place (see rear panel description), both filters must be switched into the beam path before the laser will operate. Switching either filter out of the beam path while the laser is in Ready mode switches the laser to Standby mode immediately. Inserting a filter tether into the machine while it is in Ready mode switches the machine back to Standby mode until all tethered filters have been verified to be in place.

WARNING!

Do not attempt treatment if aiming beam is not present. Patient injury may occur. The aiming beam passes down the same delivery system as the working beam; this provides a good method of checking the integrity of the delivery system. If the aiming beam spot is not present at the distal end of the delivery system, if its intensity is reduced, or if it looks diffused, these are possible indications of a damaged or not-properly-working delivery system.

** Newer Doctor Protection Filters will have less tint than older ones.

Treatment Hazards

A single treatment exposure will typically cause a blanching of target tissue. Exposure duration can be adjusted from 0.01 seconds to 2.0 seconds to result in the desired effect. A continuous treatment beam can also be selected.

NOTE: In CW, depending on the thermal load of the system, the system may shut down in safety mode prior to the footswitch being released.

Excessive combinations of power and exposure can cause undesirable tissue vaporization and charring. Reports 1 through 6 (listed as footnotes at the end of this section) indicate these hazards are no different from adverse effects from continuous wave argon lasers used at these same settings. No evidence of non-thermal effects has been observed.

Contra Indications

Patients with a condition that prevents visualization of target tissue (cloudy cornea, or extreme haze of the aqueous humor of the anterior chamber or vitreous humor) are poor candidates for LIO delivered laser treatment.

Side Effects

Corneal burns, inflammation, loss of best-corrected visual acuity, loss of visual field, and transient elevations in intraocular pressure can occur as a result of ophthalmic laser treatment. Unintentional retinal burns can occur if excessive treatment beam power or duration is used.

Laser Safety

Back scattered radiation is of low intensity and is not harmful when viewed through a protective filter. All personnel in the treatment room must wear protective eyewear, OD 4 or above at 532 nm, when the system is in Standby/Ready mode as well as during treatment. The doctor protection filter is an OD greater than 4 at 532 nm.

WARNING!

Use of controls or adjustments or performance of procedures other than those specified herein, may result in hazardous laser radiation exposure.

CAUTION

Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Footnotes for Laser Safety section:

- 1 Ludwig, K.; Lasser, T.; Sakowski, H.; Abramowski, H.; Worz, G. (Augenklinik, Universitat Munchen) "Photocoagulation in the edematous and non-edematous retina with the cw-laser of different wavelengths." *Ophthalmologe (GERMANY)*, December 1994, Volume 91, No. 6, p783-788.
- 2 Roider, J.; Schiller, M.; el Hifnawi, E.S.; Birngruber, R. (Augenklinik, Medizinische Universitat zu Lubeck) "Retinal photocoagulation with a pulsed, frequency-doubled Nd: YAG laser (532 nm)." *Ophthalmologe (GERMANY)*, December 1994, Vol. 91 No. 6, p777-782.
- 3 Wyman, D.; Wilson, B.; Adams, K. (Medical Physics Department, Hamilton Regional Cancer Centre, Ontario, Canada) "Dependence of laser photocoagulation on interstitial delivery parameters." *Lasers Surgical Medical (UNITED STATES)*, 1994, Vol. 14 No. 1, p59-64.
- 4 Obana, A.; Miki, T.; Matsumoto, M.; Ohtsuka, H.; Moriwaki, M.; Kamo, M.; Mii, T.; Kijima, M. (Department of Ophthalmology, Osaka City University, Medical School, Japan) "An experimental and clinical study of chorioretinal photocoagulation using a frequency-doubled Nd: YAG laser." *Nippon Ganka Gakkai Zasshi (JAPAN)*, September 1993, Vol. 97 No. 9, p1040-1046.
- 5 Mordon, S.; Beacco, C.; Rotteleur, G.; Brunetaud, J.M. (INSERM - National Institute of Health and Medical Research - Lille, France) "Relation between skin surface temperature and minimal blanching during argon, Nd-YAG 532, and CW dye 585 laser therapy of port-wine stains." *Lasers Surg Med (UNITED STATES)* 1993, Vol. 13 No. 1, p124-126.
- 6 Jalkh, A.E.; Pflibsen, K.; Pomerantzeff, O.; Trempe, C.L.; Schepens, C.L. (Eye Research Institute of Retina Foundation, Boston, MA 02114) "A new solid-state, frequency-doubled neodymium-YAG photocoagulation system." *Arch Ophthalmol (UNITED STATES)* June 1988, Vol. 106 No. 6, p 847-849.
- 7 Wavelengths, Ophthalmology, July 1986, Volume 93, Number 7, Page 956.

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SECTION TWO DESCRIPTION

INTRODUCTION

The *Constellation®* Vision System is a multi microprocessor-controlled ophthalmic surgical instrument with associated memory and input/output (I/O) circuitry.

The system communicates with the user via its Front Panel display, with voice confirmations, and with tones.

An automatic self-test is initiated each time the system power is turned on. If the system does not pass the self-test, either a Fault screen or an error message is displayed depending upon the cause of the issue. When the system successfully completes the self-test, it automatically goes into the Setup mode.

This section of the manual describes the system hardware, the user interface, and the accessories that may be used with the system.

FRONT PANEL

Fluidics Module

The fluidics module is located in the center of the front panel. The module allows fast and easy insertion of the cassette that contains all the fluidics connections required for surgery.

Front Display Panel and Touch Screen

The 17-inch front display panel tilts and extends forward to allow easy positioning during setup and surgery. The front display is the user's main source of system control, allowing fingertip command of system functions throughout the enhanced graphical user interface.

A data card slot is located just beneath the LCD display. A data card (SD Memory Card) can be inserted into this slot when the user wants to back up or restore system settings. A 2 GB SD memory card is the maximum size that the system will recognize. Larger capacity memory cards are not recognizable by the system and if inserted, will lock up the system until removed.

Pneumatic and Electrical Connectors

The *Constellation®* Vision System console contains two vertical columns of connectors, located on the left side of the cassette, for surgical probes and handpieces. The right column is for pneumatic probes, and the left column is for electrical handpieces.

LED Rings - The rings surrounding each front panel connector automatically illuminate in a particular color to guide the user in making the proper connection to the system as follows:

- Blue - A surgical tool is selected by the user in Setup or a surgical tool is related to the current Step in surgery.
- Green - The system has detected that the appropriate surgical tool has been connected to the port.
- Amber - The system has detected, via RFID, a surgical tool that is not appropriate for the port or is invalid for other reasons.

Note: The green and amber lights have higher priority than the blue light; therefore, it will illuminate only if no other light is applicable.

WARNING!

Connect only Alcon supplied consumables to console/cassette connectors. Do not connect consumables to patient intravenous connections.

Footswitch Storage Hook

This footswitch storage hook is located at the bottom of the front panel. When the footswitch is not in use or the system is being moved, use this hook to store and protect the footswitch.

Instrument Tray (optional)

Provides a movable instrument tray within the sterile field. There is a curved metal rod on either side of the tray that allows for creation of a sterile pouch when used with sterile tray arm cover. The tray is capable of accommodating a variety of positions in the operating room environment: right, left, front and rear of the surgeon as well as the front of the bed. Refer to Section Three for detailed instructions on adjusting the tray position.

WARNINGS!

The maximum allowable load on the instrument tray is 20 lb (9 kg). If the load exceeds this limit, the tray arm will automatically lower itself in order to avoid tipping the system over. Additionally, if the instrument tray is positioned over a patient, a mayo stand should be placed beneath it to avoid a potential collapse of the tray arm onto the patient.

Place the instrument tray in the stored position as shown in Figure 2-1 prior to transportation to avoid a situation that could cause the system to tip.

IV Pole with Bottle Hanger (optional)

A bottle of *BSS*® or *BSS PLUS*® irrigating fluid is hung from the hook on top of this pole. The IV pole is used to raise and lower the bottle height, causing irrigation pressure to increase or decrease.

WARNING!

Do not use *Legacy*® IV pole extender with *Constellation*® Vision System IV pole.

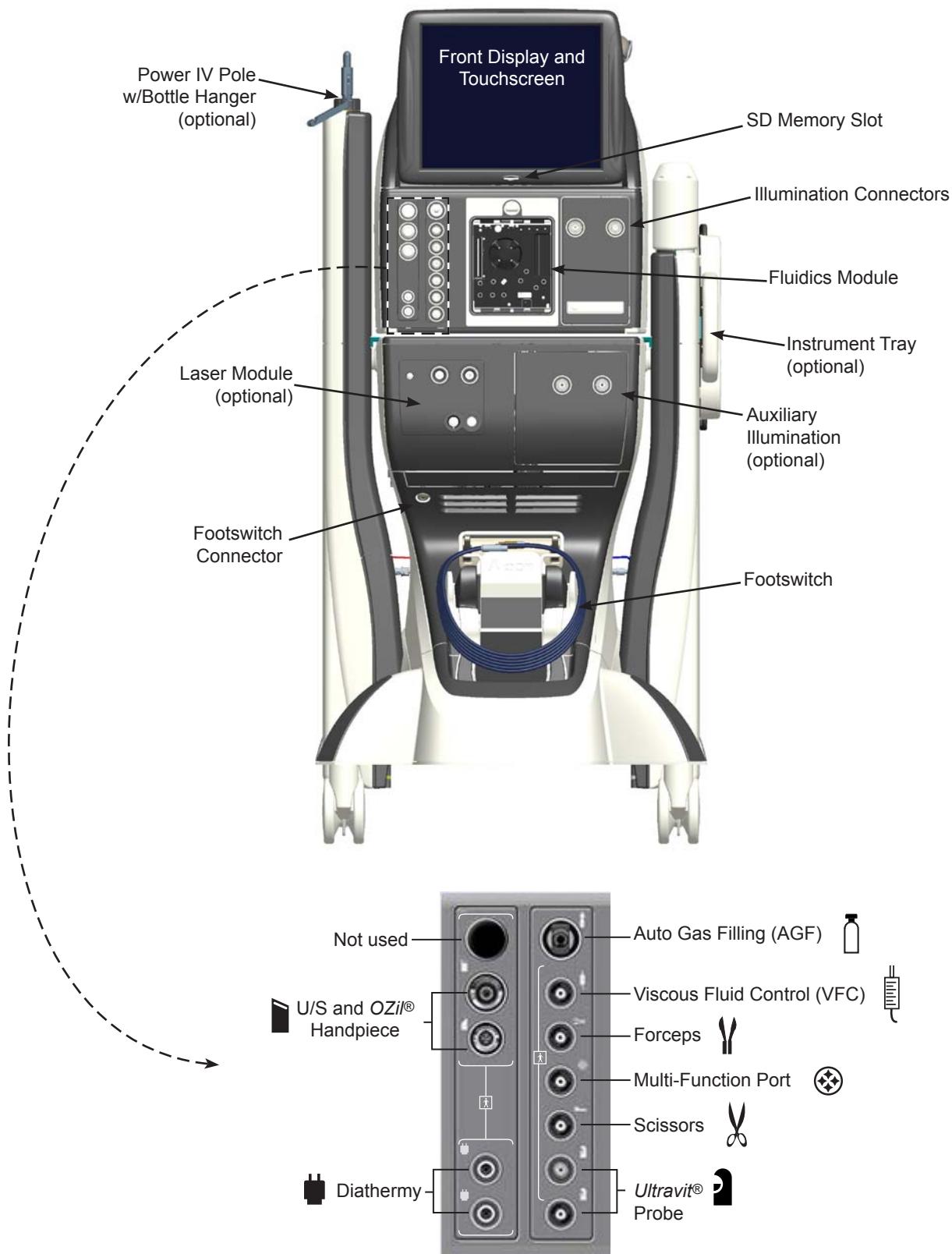


Figure 2-1 The Constellation® Vision System Console Output Connectors*

* Labels and icons may vary according to the date of manufacture and are shown here for reference only.

Caster Wheels

Four large caster wheels support the *Constellation®* Vision System. The wheels rotate 360° for ease of system mobility, and have a locking lever to secure the system in place. The wheels should always be locked (handle down) when the unit is in use, and unlocked when being moved.

The locking levers have three positions as follows:

- Up arrow position - The caster wheel directional movement will lock in the 0 or 180 degree position. The wheel rotates freely.
- Unlocked icon position - The caster wheel has 360 degrees of directional movement and the wheels rotate freely.
- Locked icon position - The caster wheel directional movement and wheel rotation are both locked.

Illumination

Primary illumination is provided by two independently controlled ports located just below the display. The light output at these ports is based on xenon arc lamp technology that generates high brightness white light. Each port will allow the use of 20, 23, and 25 GA ACMI terminated fiber probes and provides the following minimum output for the probes (100% setting; 0-200 hours of lamp use):

- 20 GA probes = 16 ± 6 lumens (@115% set point¹; 0-400 hours of lamp use)
- 23 GA probes = 23 ± 13 lumens (@115% set point¹; 0-400 hours of lamp use)
- 25 GA probes = 23 ± 13 lumens (@115% set point¹; 0-400 hours of lamp use)

¹ Based on a representative nominal UFR fiber.

Auxiliary illumination is available as an optional feature that provides for two additional channels of high brightness white light.

Laser (optional)

The optional laser module is a diode-pumped solid-state type laser designed for ophthalmic use. This laser delivers a visible 532 nm green treatment beam, and a visible 635 nm Diode Laser aiming beam (635 nm is an approximate value between 630-640 nm).

Footswitch Connector

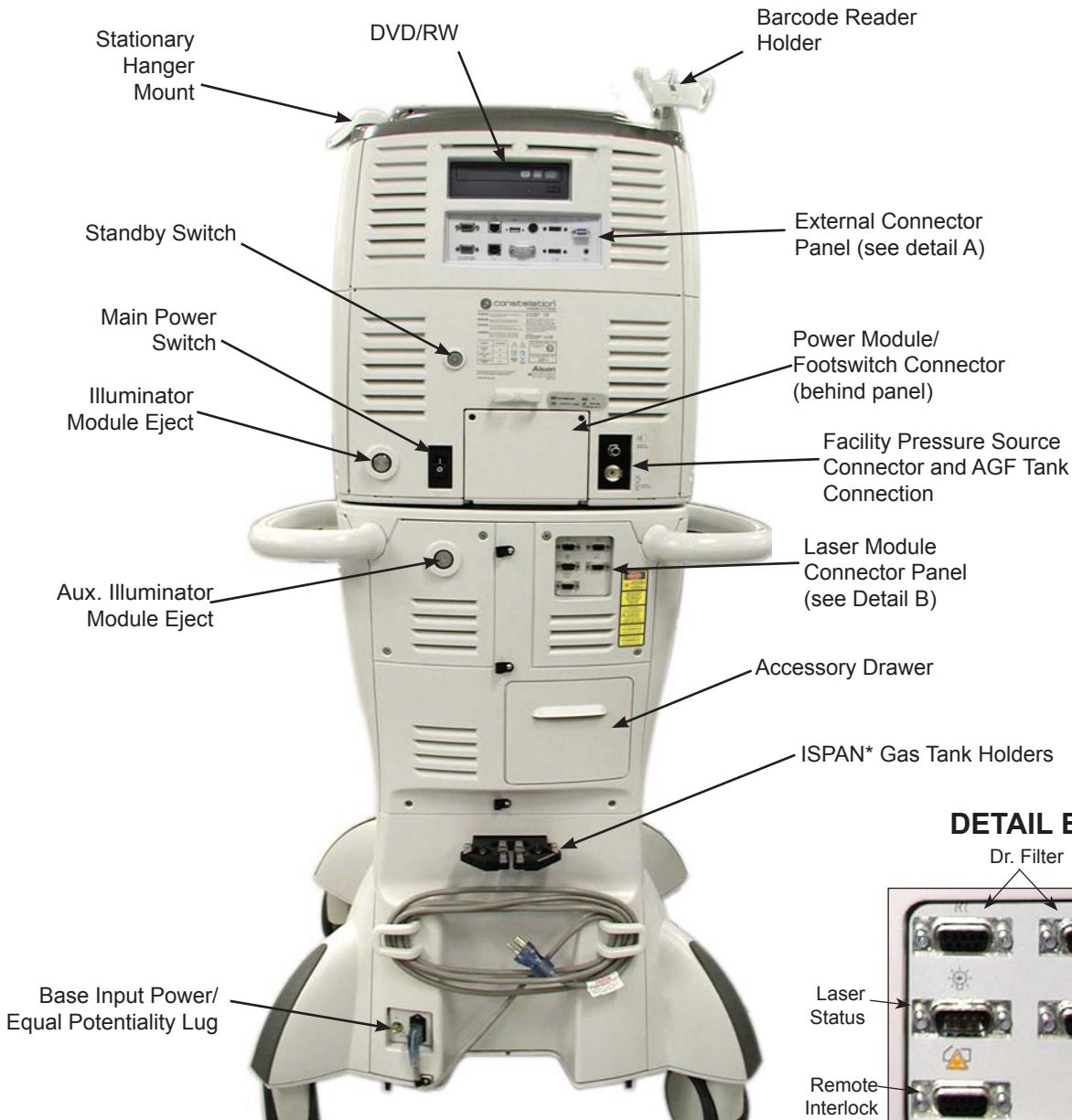
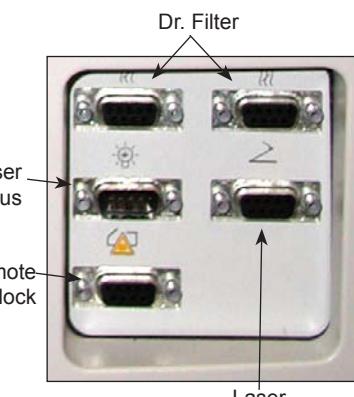
The footswitch connector is located on the front panel and is used to connect the *Constellation®* Vision System footswitch to the console. (In the monolith configuration shown in Figure 2-1, the footswitch connection is made in the front of the base.)

Handles

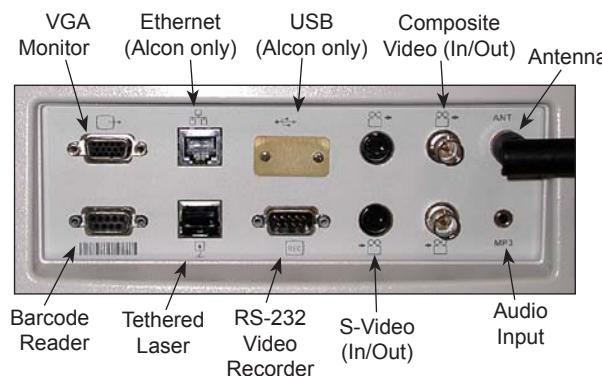
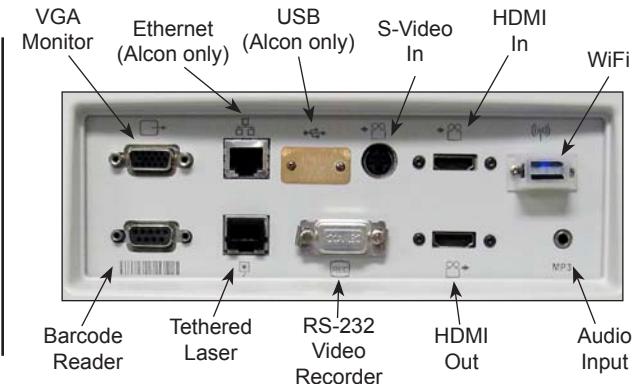
Handles are located on the sides and back of the instrument, and should always be used to move the unit. For safety and control, the unit should be pulled, not pushed.

CAUTION

The system must be moved carefully, otherwise the system could tip over and become damaged. Do not push or pull the unit by the display, the tray, or the IV pole. Handles located at the rear and sides of the unit are provided for moving the instrument. The unit should be pulled and not pushed, especially over elevator and door thresholds.

REAR PANEL**DETAIL B****DETAIL A**

(System will use one of the two connector panels shown below)

A-1**A-2****Figure 2-2** The Constellation® Vision System Rear Panel

DVD/RW

The DVD player/recorder allows for software upgrades to the system and data/settings transfer.

Bar Code Reader

The bar code reader allows the operator to quickly scan consumables into the system. When a consumable is scanned through the reader and the system recognizes the bar code as one that is preconfigured in the system, an audible beep is sounded and the associated consumable is added to the current surgical case. If the bar code is not recognized by the system then an advisory message is displayed along with an audible beep.

The operator can verify the bar code has been properly entered into the system by tapping the Consumables button to bring up the Consumables list window.

External Connectors

This module, located in the middle of the rear panel, contains various connectors and outlets used for electrical interconnections. The system will have one of the two connector panels shown in Figure 2-2.

Figure 2-2, Detail A-1

- VGA out - External VGA monitor connection
- Ethernet - Alcon use only
- USB Connector - Alcon use only
- Composite Video In/Out - Used for Video Overlay
- Antenna - Used for wireless communication
- Serial Connector - Used for Video Recording
- Bar Code scanner connection
- S-Video In/Out - Used for Video Overlay
- Tethered Laser Connection - see Section Three for instructions on the tethered laser configuration.
- Audio Input - MP3 player audio input

Figure 2-2, Detail A-2

- VGA out - External VGA monitor connection
- Ethernet - Alcon use only
- USB Connector - Alcon use only
- S-Video In - Used for Video Overlay
- HDMI Video In/Out - Used for Video Overlay
- WiFi - Used for wireless communication
- Serial Connector - Used for Video Recording
- Bar Code scanner connection
- Tethered Laser Connection - see Section Three for instructions on the tethered laser configuration.
- Audio Input - MP3 player audio input

CAUTION

The USB connector () and service ethernet connector located on the rear panel are for use by Alcon trained personnel only. Failure to comply will void warranty.

Power Module/Footswitch Connector

This module contains the power and footswitch connection from the base unit.

Facility Pressure Source Connectors

This connection is provided to connect the console to the facility pressure source (air or nitrogen). Refer to Section Three for detailed instructions on connecting a pressure source.

Laser Module Connector Panel (Figure 2-2, Detail B)

- Dr. Filter Connections - Provides connections to standard Alcon Dr. Filters.
- Laser Footswitch Connection.
- Remote Interlock - connection to accommodate the room-interlock functionality. When a controlled entrance is opened, this interlock interrupts the operation of the laser until the door switch contact is closed.
- Laser Status - Connection to accommodate a “Laser On” indicator. This provides an electrical signal to an external facility sign that indicates when the laser is in the ready state.

Accessory Drawer

One drawer allows the storage of miscellaneous accessories.

Base Input Power

Connection to connect the *Constellation®* Vision System to facility power.

Equipotential Ground Connector

The Equipotential Ground Connector may be used to provide a direct connection between the *Constellation®* Vision System and the potential equalization bus-bar of the electrical installation. This connector complies to the requirements of IEC/EN 60601-1.

Auxiliary Illuminator Module Eject Button

Pressing this button causes the optional auxiliary illuminator module to release and enables its removal from the front panel for lamp replacement by trained personnel only.

Illuminator Module Eject Button

Pressing this button causes the illuminator module to release and enables its removal from the front panel for lamp replacement by trained personnel only. **NOTE: The illuminator module should only be ejected or inserted when the system is powered off.**

Main Power Switch

Connects AC power to the system.

Standby Power Switch

This push-button switch is used to turn secondary power ON and OFF. If system freezes and is unresponsive to operator commands, press Standby switch for fifteen seconds to shut down system, then re-boot.

Stationary Hanger Mount

Used to hang a bottle of sterile intraocular irrigating solution.

FOOTSWITCH

Functional operations of the *Constellation®* Vision System console are controlled by the footswitch shown in Figure 2-3. The footswitch consists of a treadle, left and right horizontal/vertical switches, left and right heel switches, and a tension adjustment knob. An advisory popup window is displayed if the footswitch is not connected.

Generally, the treadle is used to provide control of a parameter, such as vacuum, with the treadle's angle of depression proportional to the parameter output. In some modes of operation, the treadle is used to provide on/off control of a function, with any depression resulting in a fixed output of its parameter.

The footswitch treadle is used in a mode-dependent fashion during system operation. In U/S mode for example, when the treadle is depressed its range of travel is divided into ranges 0, 1, 2 and 3. Each range is separated from the previous range by a detent. Detent firmness levels are programmable in the *Doctor Settings menu* which is discussed later in this section of the manual (see *Settings*). The footswitch icon located in the upper left corner of the screen displays the current treadle position.

Right and left switches are used to enable and disable system functions. The switches are nudged sideways (horizontal) for some functions, and pressed down (vertical) for others.

The tension adjustment knob, located on the front of the footswitch, is used to adjust the pressure needed to depress the treadle.

CAUTION

Never pick up or move the footswitch by holding the cable. Damage may result.

NOTE:
The *Constellation®* footswitch does not fire the optional laser.

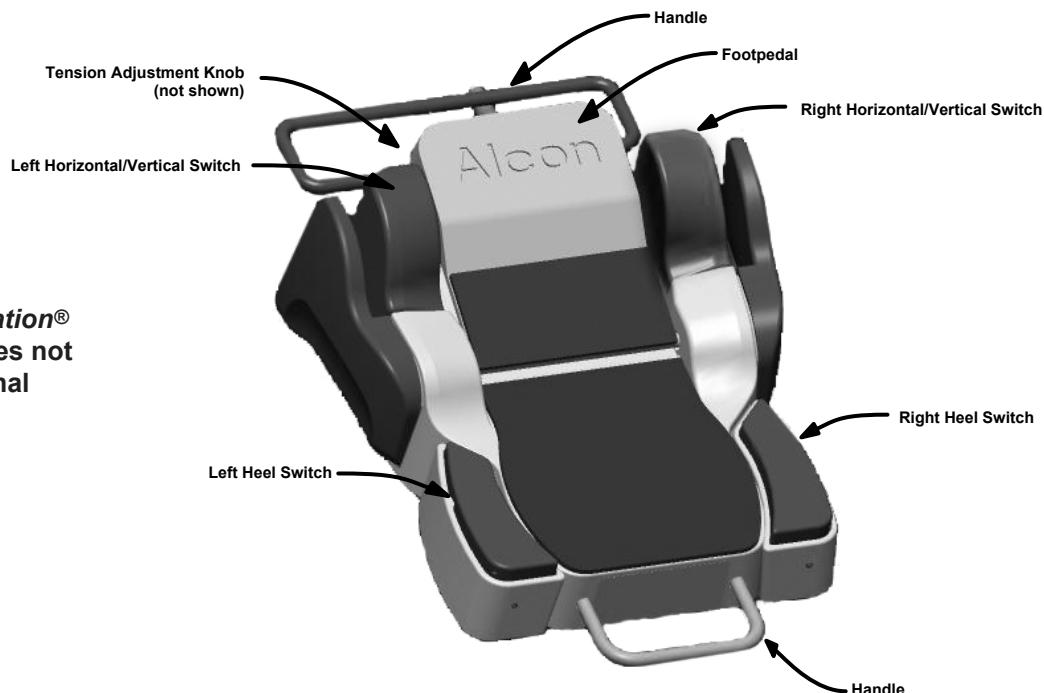


Figure 2-3 The *Constellation®* Vision System Footswitch

REMOTE CONTROL

The Remote Control is a wireless, handheld, battery operated device that uses infrared light to communicate with the *Constellation®* Vision System console. Each of the different keys on the Remote Control unit has its own unique key code that is transmitted to the *Constellation®* Vision System console when the key is pressed. The transmitted key codes are translated into commands that control the *Constellation®* Vision System console.

WARNING!

The Alcon remote control is common to several Alcon instruments. To keep the remote from interfering with other Alcon instruments, each remote control must be set to match the unique channel (A, B, C, or D) of its associated instrument. Changing batteries will cause the remote to default to channel A; therefore the remote may need to be reset to the instrument's unique channel as described in "Selecting Remote Control Channel" on page 2.11.

CAUTION

Do not sterilize the remote control as it will damage the unit.

Figure 2-4 shows the Remote Control and the keys provided. When a Remote Control Transmitter key is pressed, the *Constellation®* Vision System console determines whether or not the key press was valid and generates an appropriate valid or invalid key tone.



Figure 2-4 The *Constellation®* Vision System Remote Control

The Remote Control is divided into three sections from top to bottom. The three sections of the display screen are 1) the top section is for Global Selection and adjustments of global values, 2) the main (middle) window is for surgery screen navigation and parameter settings, and 3) the bottom section is for selecting steps and enabling/disabling selected controls. Some items on the *Constellation®* Vision System console display screens are not accessible with this Remote Control unit.



Global Control Up/Down Keys

The Global Control up/down keys on the remote control function as they do on the Host Display touchscreen. Each individual press of the up arrow key increments the setting on the selected global control in the Globals panel on the touchscreen. Each individual press of the down arrow key decrements the setting on the selected global control. To move rapidly up or down, the key is pressed and held until the desired setting is reached.



Global Controls Navigation Key

The Global Controls Navigation key enables the user to navigate to any control on the Globals panel and select a specific control. Pressing this button the first time selects the Infusion Control which is the first control on the Globals panel. The selected control will be highlighted with a golden outline. Each successive press of the Global Controls Navigation key causes the next available control on the Globals panel to be selected. An exception to this rule occurs if the Infusion Control is selected. In this case the IOP Compensation button on the control is selected to adjust IOP settings.



Surgery Screen Navigation Key

The Surgery Screen Navigation key is a four way switch that enables a remote control user to move up, down, left and right on the surgery screen and to select the controls and/or panels on the screen. Once a control is selected, the user can press the Parameter Value Adjustment keys to increase/decrease the control parameters.

The Navigation Key is valid when the Surgery screen is being shown, but is invalid when a popup is displayed.



Parameter Value Adjustment Up/Down Keys

The Parameter Value Adjustment Up/Down keys are used to adjust settings (parameters) in a Surgery Control Panel that have adjustment arrows (i.e., pressure, vacuum, cut rate). Surgery control panels are selected via the Navigation Key and a blue border indicates the panel that is selected.



Previous Step/Next Step Keys

The Previous Step/Next Step keys are used to move left and right through the surgery steps at the bottom of the Surgery screen. In the Surgery screens, when the Previous Step/Next Step key is pressed on the remote, the system selects the next step to the left or to the right. If it is a valid step, it will be selected immediately without having to press any other keys. Continuing to press the keys causes the system to move through the steps and wrap around to the beginning step. It is not possible to access the submodes from the Remote Control Unit.

The Previous Step/Next Step keys can also be used in an information popup to select a button (e.g., OK, Cancel, Save, etc.).



Enter Key

The Enter key is used to enable/disable a selected control. For example, if the vacuum control On/Off button is selected (highlighted with a gold border), pressing the Enter key alternately toggles the control On and Off.

The Enter key is also used to move through the submodes of a surgery step. If the current surgery mode has submodes, pressing the Enter key once causes the submodes to be highlighted with a gold border. Additional presses of the Enter key (while the submodes are highlighted) causes the system to select the next submode to the right and eventually wrap around to the leftmost submode.

Remote Control Batteries

When the batteries in the remote control are low, the status message “Remote Battery Low” will appear in a popup dialog the first time a key is pressed after the system is turned on. The message will disappear after new batteries are installed and a remote control key is pressed. A battery holder inside the remote holds three (3) AAA (LR3) batteries.

Selecting Remote Control Channel

The remote control can be configured to operate on one of four channels. This feature allows four remote controls to independently control four *Constellation®* Vision Systems operating in the same room or area. Remote controls are factory preset to channel A. For proper remote operation, the *Constellation®* Vision System must be set to the same channel as the remote.

The Option/System Settings/Remote Control window allows the selection of four remote receive codes: A, B, C, & D. This selection must correspond to the channel selection on the remote control. Set the remote channel as instructed below.

To select a remote channel on the *Constellation®* Vision System:

1. Press the **Options** button to open the Options popup screen.
2. Press the **System** button to bring up the System Settings screen.
3. Press the **Remote Control** tab to display the Remote Control Settings screen (see Figure 2-5).
4. Hold the remote control in front of the *Constellation®* Vision System display screen and simultaneously press its **parameter value adjustment up/down** keys. After the system emits a sound acknowledging the action, simultaneously release the buttons.
5. On the remote control, press the **Navigation** key corresponding to the new channel as labeled in the Remote Control Settings screen.
6. On the display, press the **Save** button to save the change (pressing Enter twice on the remote also saves the change), or press **Cancel** to return to the main screen without saving the changes.

No additional steps are needed once the remote channel is set, and only one remote channel is stored per unit.

NOTE: The Alcon remote control is common to several Alcon instruments. If necessary to distinguish between remote controls, identify the remote controls and the units with unique labels.

CAUTION

Do not sterilize the remote control as it will damage the unit.



Figure 2-5

Remote Control Channel Selection Screen (Options\System\Remote Control tab)

FRONT PANEL DISPLAYS AND TOUCHSCREEN

The *Constellation®* Vision System front display panel and touch screen has a flat, non-glare surface, and is mounted above the console. Control buttons are located within the active touch screen area. There are three basic types of push-button on the display screen: up/down arrow buttons, sliders, and momentary buttons. The user can press and hold the up/down arrow buttons until the desired adjustment is complete, or press the momentary buttons with a single push-and-release to activate a function.

The *Constellation®* Vision System emits an audible tone to indicate button activation. Activation of a valid touchscreen button or remote control button results in a valid key tone; an invalid button results in an invalid key tone, and, in some circumstances, its icon symbol is ghosted to indicate an invalid function.

There are four types of display screens: the Setup screen, Surgery screens, End Case, and Popups (sometimes referred to as dialogs).

- The Setup screen is used to prepare for surgery; i.e., connecting instruments, priming the fluidic management system and testing the handpiece.
- Surgery screens contain surgical settings for each of the current surgical procedures. Settings can be adjusted by pressing the touch screen buttons for the associated controls.
- The End Case screen provides the user with a summary of the case and a tabbed interface area for display of the various metrics associated with the case.
- Popups are displayed as a result of selecting an option from the Options drop list (i.e., System Settings, Doctor Settings, etc.) or pressing the Footswitch button. Popups enable the user to view and modify system settings, doctor settings, and some surgical settings. There are also popups displayed to advise or warn the user of a situation, or to indicate progress on a function in the Setup screen.

Startup Screen

Upon power-up of the system, an introductory screen is displayed as shown in Figure 2-6 while the system completes initialization and self-test diagnostics. All user inputs are locked out while this screen is displayed. If initialization is successful, the main screen is displayed as shown in Figure 2-7.



Figure 2-6 The Startup Screen

Main Screen

The main screen is divided into three areas: Menu Bar, Globals, and the System State area as shown in Figure 2-7. The Menu Bar provides selections that are available in any system state. The Globals area provides control of functions that are available in all surgical modes and for any system state. The System State area provides specific information for one of the following available states: Setup, Surgery, or End Case. These states are selected by pressing the associated tab in the menu bar. Figure 2-7 shows the Setup state.



Figure 2-7

The Main Screen

Menu Bar

Figure 2-8 below shows the Menu Bar section of the screen. This portion of the screen is always available regardless of the System State. The menu bar allows the user to change various high-level functions as well as certain system options.

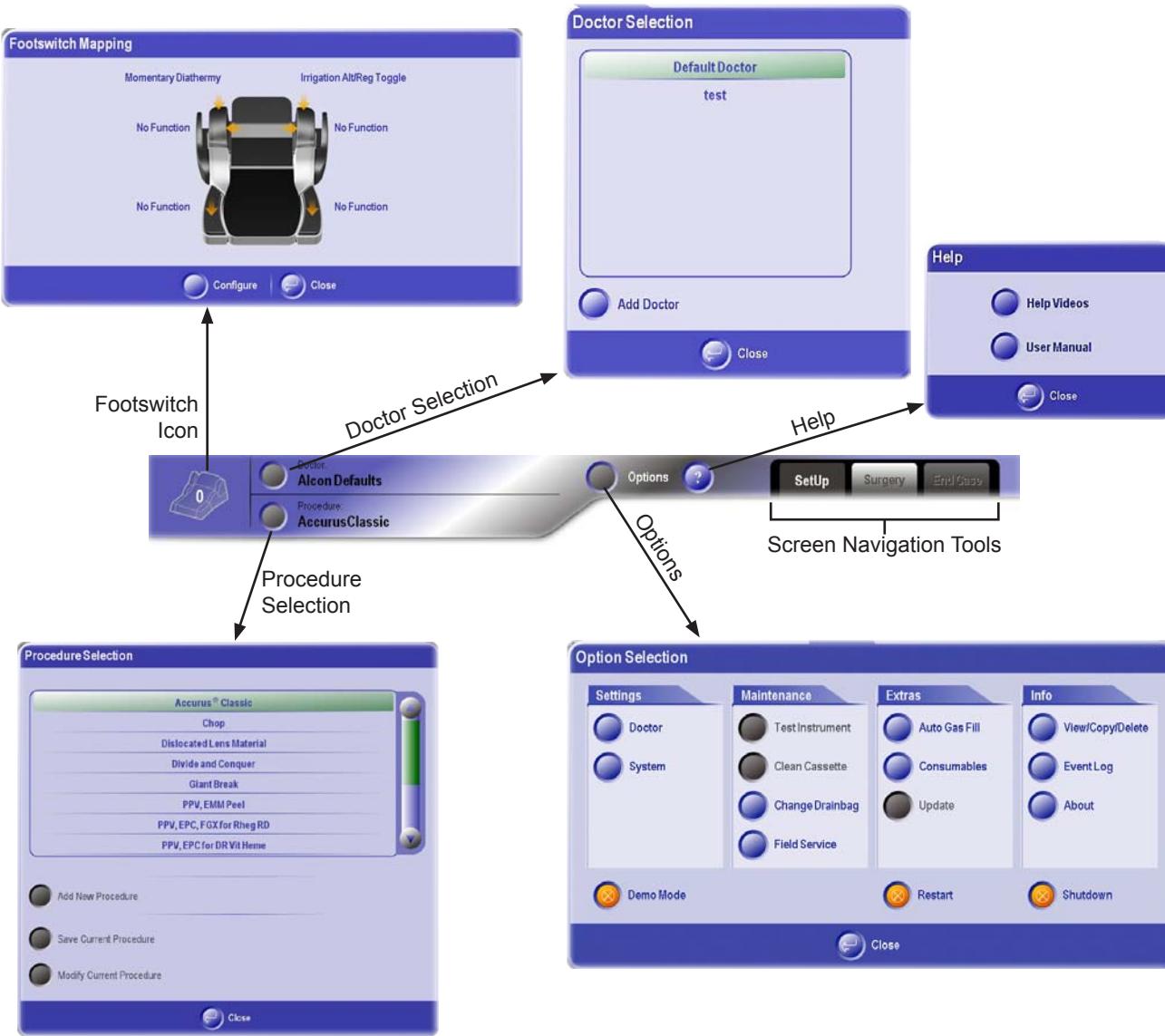


Figure 2-8 The Main Screen Menu Bar

Menu Bar: Footswitch Icon

The Footswitch icon provides feedback relating to the current state of the main console footswitch as follows:

- The icon displays the current position of the treadle indicated by the number shown on the icon.
- When a button on the footswitch is pressed, the icon shows which button and, when applicable, which way it was pressed.

Selecting the Footswitch icon displays the Footswitch popup shown in Figure 2-8. This popup shows the footswitch with labels indicating the current mapping for each button. Pressing the Configure button closes the popup box and displays the Doctor Settings screen with the Footswitch tab selected. In this screen the footswitch can be configured as desired. Refer to *Doctor Settings/Footswitch* later in this section for detailed information on configuring the footswitch.

Menu Bar: Doctor Selection

Pressing the Doctor Selection button displays a popup with the names of all available doctors. Selecting one of the entries will change the currently selected doctor and also update the current procedure and – if in surgery – the current step.

New doctors can be added to the list by pressing the “Add Doctor” button. When this entry is selected, a keyboard is displayed allowing the user to enter a new doctor. The new doctor is automatically selected if the name is valid (the name cannot be more than 40 characters or a duplicate name). If the name is identical to a doctor already in the system, an advisory is displayed.

Menu Bar: Help (?) Button

Pressing the Help (?) button displays a popup that provides selections to display Help Videos and the User Manual.

Menu Bar: Procedure Selection

The Procedure Selection popup (see Figure 2-8) contains the names, sorted alphabetically, of all available procedures for the current doctor with the currently selected procedure highlighted. To select another procedure, simply press the desired procedure. The procedure will become highlighted and the popup will close. The Close button can be used to exit the popup without changing the procedure.

Pressing the "Add New Procedure" button starts the process of adding a new procedure to the list of available procedures for the currently selected doctor. Refer to the following section entitled "Adding a New Procedure" for detailed instructions on adding a new procedure and a description of the screens used to setup the procedure.

ADDING A NEW PROCEDURE...

To add a new procedure to the list of procedures available to the current doctor, follow the steps below:

1. Press the "Add New Procedure" button in the Procedure Selection popup.
A keyboard is displayed allowing the user to name the new procedure.
2. Using the keyboard, enter the name of the new procedure then press "Save".
The keyboard popup closes and the Modify Procedure dialog is displayed as shown in Figure 2-9.

The Modify Procedure dialog is used to create custom surgical procedures. The popup presents a scrollable list of available surgical steps the user can add to the procedure being created or modified. **Note: Procedures can also be modified in Surgical mode by pressing the Modify button.** In addition to adding steps, the user can also remove, rename, and move steps within the current procedure. The steps can be manipulated using the buttons in the Modify Procedure dialog or by Drag-and-Drop functionality; i.e., press and drag the step icon to the new location.

In general, customization of a procedure is performed by selecting a step from the list of available source steps in the Procedure Manager and inserting the step into a list of destination steps in the upper panel named "In Procedure". Only the current procedure can be modified. The available steps in the Procedure Manager can be filtered as desired using the selections in the "Filter by:" drop down menus.

Creating Or Editing Procedures

As shown in Figure 2-9, the name of the current procedure is shown at the top of the screen. This is followed by the steps comprising the current procedure. Below the current procedure steps is the Procedure Manager which contains a complete library of steps that can be added to the current procedure.

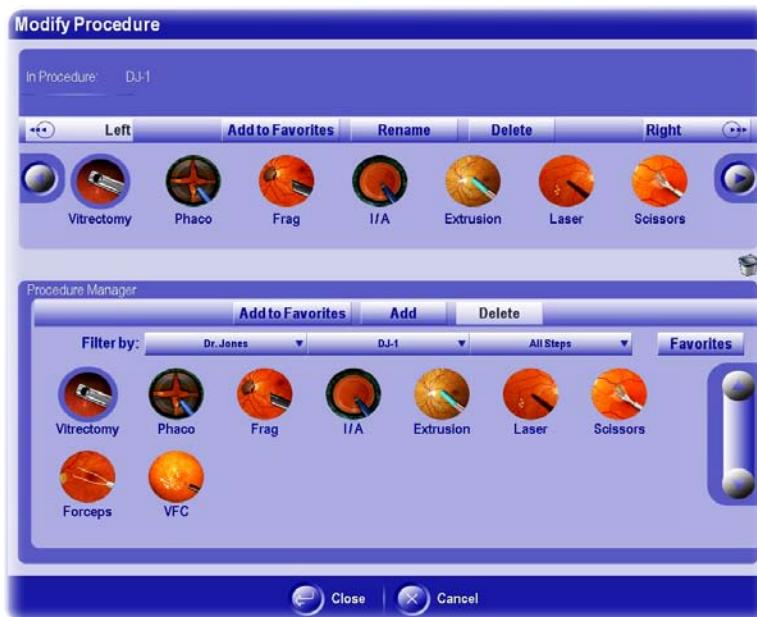


Figure 2-9 Procedure Modify Screen

The items on the Modify Procedure dialog are defined and operate as follows:

In Procedure: xxx - Displays the name of the procedure to be modified.

Left button - Moves the selected step one position to the left.

Add to Favorites button - Adds the selected step to the Favorites panel.

Rename button - Opens the keyboard popup to enable renaming of the currently selected step.

Delete button - Deletes the selected step from the list.

Right button - Moves the selected step one position to the right.

Arrow buttons - Scrolls the list of steps left or right.

Procedure Manager Panel - This panel contains the list of steps available for insertion into the In Procedure list. Pressing the arrows on the scroll bar scrolls through the complete list. Also included in this panel are the following filters:

- *Add to Favorites button* - Adds the selected step to the Favorites panel.
- *Add button* - Adds the selected step to the list of steps in the current "In Procedure" steps list.
- *Doctor Step Filter* - Restricts the available steps to those belonging to the specified doctor's procedures.

- *Procedure Step Filter* - Restricts the available steps to those belonging to the specified Procedure.
- *Mode Step Filter* - Restricts the available steps to those belonging to the specified Step.
- *Favorites* - Pressing this button displays the steps that have been added to the current doctor's Favorites list.

Trash icon - Allows for removal of the selected step from the In Procedure steps list or Favorites List by dragging the step onto the icon.

Close button - Closes the popup and saves all changes to the current procedure.

Note: The changes are saved in temporary memory only. To save changes after the system has shut down, the procedure must be saved from the Quick Save popup. If no steps are in the procedure an error message is displayed saying, "At least one step must be added to the procedure".

Cancel button - Closes the popup and discards all changes made to the current procedure.

EDITING THE CURRENT PROCEDURE:

1. To filter the available steps listed in the Procedure Manager, set the Doctor, Procedure, and Mode Step filters so that only the desired steps are shown. The system default is to show all available steps.
2. To add a step to the current procedure, select a step from the Procedure Manager steps list and then press the Add button. When pressed, the selected step is inserted into the In Procedure panel at the position immediately following the currently selected procedure step. Alternatively, the same action can be performed by selecting and dragging the step into the In Procedure panel. To ensure step name uniqueness, if the name of the added step matches the name of an existing step in the procedure, the step name is modified by appending a numeric suffix (e.g. Vitrectomy2).
3. To move a procedure step to the left or right, select the step and drag it to the left or right. Alternatively, select the step and press the left or right buttons.
4. To remove a step from the procedure, select the step from the procedure then press the Delete button.

EDITING THE FAVORITE STEPS LIST:

1. To add a step from the procedure to the list of Favorites steps, select the step from the procedure then press the Add to Favorites button. Upon being pressed, the procedure step will be added to the end of the Favorites list. If a step is added which has the same name as an existing Favorite Step, a prompt is displayed stating: "Overwrite existing favorite step with the same name?" If the user replies Yes, the existing Favorite Step is overwritten. If the user replies No, the keyboard is displayed allowing a new step name to be entered.
2. To delete a Favorites step from the Favorites list: press the Favorites button, select the step from the list and press the Delete button.

Menu Bar: Options

Pressing the Options button on the Menu Bar displays the Option Selection popup shown in Figure 2-8. Each of the four tabs contains various options that may be adjusted.

SETTINGS: Doctor; System

MAINTENANCE: Test Instrument; Clean Cassette; Change Drainbag; Field Service

EXTRAS: Auto Gas Fill; Consumables; Update

INFO: View/Copy/Delete; Event Log; About

DEMO MODE: The *Constellation®* System “Demo Mode” allows the user to interact with the user interface without being affected by missing or non-functional hardware. For example, in Demo Mode the user can program certain screens without having any source pressure connected. The only visible difference is that "DEMO MODE" is displayed in yellow text in the upper left corner of the display above the footswitch icon.

For additional details on using the system in Demo Mode, refer to the section entitled "Demo Mode" later in this section of the manual.

RESTART button: Pressing this button causes the system to reboot and then return to the setup screen. Restarting the system may be required if the system displays a system fault.

SHUTDOWN button: Pressing this button causes the system to shut down.

CLOSE button: Exits the popup.

Menu Bar: Options - DOCTOR SETTINGS

Selecting Doctor from the Options menu displays the screen shown in Figure 2-10. It allows the user to specify doctor specific configurations in the following areas as indicated by the tabs at the top of the popup window:

- General Preferences
- Surgical Preferences
- Footswitch programming of buttons and treadle
- Laser settings including laser footswitch programming
- Volume levels for all sounds

The Save, Cancel, and Revert to Defaults buttons apply to all tabs.

- **Save Button** - Saves the modified items on all the doctor settings tabs and also applies the settings to the current surgery screen (if applicable).
- **Cancel Button** - Exits the popup without saving or applying any settings.
- **Revert To Defaults Button** - Resets all the configurable items on the current settings tab to default values.

Menu Bar: Options - DOCTOR SETTINGS - GENERAL

The General Preferences tab contains the following items:

- Language - Drop down list that allows the user to select the language for labels and annunciations. The drop list contains an entry for English and for each language pack installed on the machine.
- Heel Double Click - This selection determines whether or not heel double click functionality is available. Choices: Enabled or Disabled.
- PIN - This section allows the user to add a Personal Identification Number (PIN) that must be entered before accessing that doctor's settings.
 - *Add Button* - Pressing the Add button displays a numeric keypad that enables the user to enter a PIN. The PIN must be entered twice before it can be saved in the numeric pad dialog. Not present for Default Doctor.
 - *Modify Button* - Allows the user to change an existing PIN for a doctor. Not present for Default Doctor.
 - *Delete Button* - Allows the user to delete an existing PIN for a doctor. Not present for Default Doctor.
- *Standard vs. Advanced Display Modes* - The Standard display mode offers a minimum number of options on the associated panels. In Advanced display mode, the displayed panels offer optional controls for setting and configuring functions. The default mode is Standard. Advanced display mode is available in the following panels: Extraction, Vit Cutting, Ultrasound, and Vitrectomy Bimanual.
- Display Submode in Custom Procedures - This option applies to Custom procedures only. When enabled, submodes are automatically displayed on the step panel. When disabled, submodes are not displayed unless the user taps the step icon in the step panel.



Figure 2-10 The Doctor Settings Popup - General Tab (Options\Settings-Doctor\General)

Menu Bar: Options - DOCTOR SETTINGS - SURGICAL

The Surgical tab contains three sub-tabs that are related to surgery: Infusion/Irrigation, Reflux, and General

Menu Bar: Options - DOCTOR SETTINGS - SURGICAL - INF/IRR

The Inf/Irr (Infusion/Irrigation) Surgical sub-tab (shown in Figure 2-11) allows the user to change certain preferences related to infusion and irrigation during surgery.

- Infusion Units - Allows the user to specify the units (mmHg or cmH20) used for the Infusion Global control.
- Irrigation Units - Allows the user to specify the units (mmHg or cmH20) used for the Irrigation Global control and Continuous Reflux.
- Elevated Infusion Alarm Set point - Allows the user specify which infusion value should be regarded as elevated. When the current infusion setting equals or exceeds the specified value, the elevated infusion timer is started. **NOTE: The timer is applicable to both liquid and air infusion.**
- IOP Control - The IOP Control mode compensates for the pressure drop caused by fluid flowing through the infusion tubing set to provide a constant IOP. IOP compensation is available only with premium cassettes in posterior and combined surgical modes.
- IOP Control Limit - The IOP Control Limit specifies up to what infusion flow rate, compensation for the pressure drop in the infusion tubing set should be applied. At flow rates higher than the set infusion control limit, IOP will drop and no longer be maintained at the requested IOP set point. The IOP Control Limit is only applied when aspiration is turned off. Its main function is to reduce the fluid flowing out of the open trocar cannulas during instrument exchanges.

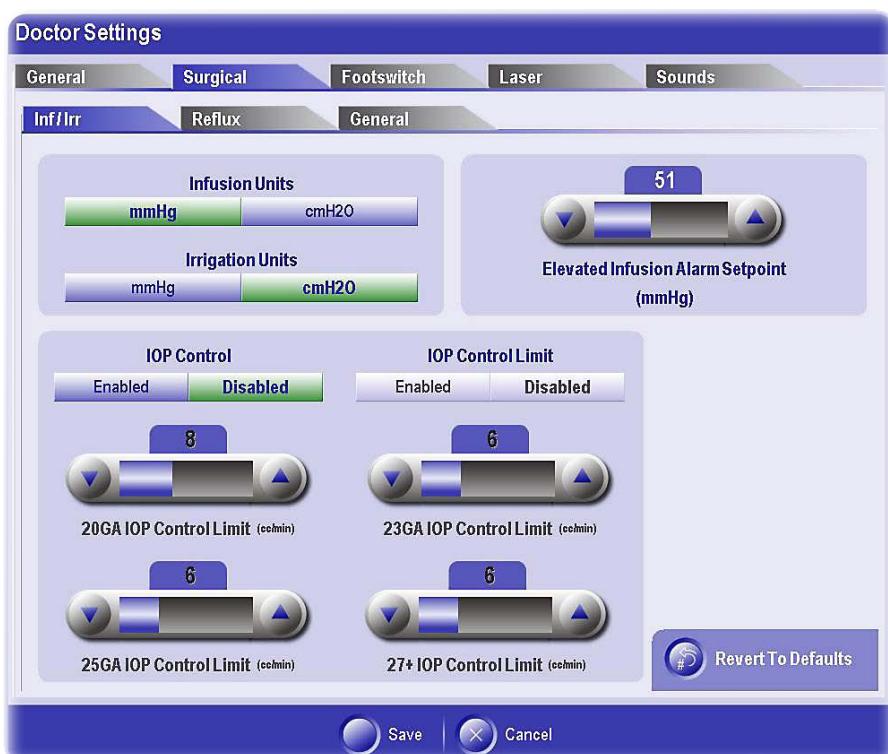


Figure 2-11 The Doctor Settings Popup - Surgical/Inf/Irr Tab (Options\Settings-Doctor\Surgical\Inf/Irr)

Menu Bar: Options - DOCTOR SETTINGS - SURGICAL - REFLUX

The Reflux sub-tab (shown in Figure 2-12) allows the user change certain preferences related to reflux during surgery.

- Posterior Reflux Mode - Allows the user to choose which reflux mode, Proportional or Micro, should be the default in the posterior steps.
- Anterior Reflux Mode - Allows the user to choose which reflux mode, Continuous or Micro, should be the default in the anterior steps.
- Proportional Reflux Set point - Allows the user to choose the set point for proportional reflux. Range: 0 – 120 mmHg.
- Micro Reflux Set point - Allows the user to choose the set point for micro reflux. Range: 10, 25, 50, 75, or 100%.
- Continuous Reflux Set point - Allows the user to choose the set point for continuous reflux. Range: 0 – 163 cmH2O.



Figure 2-12 The Doctor Settings Popup - Surgical/Reflux Tab
(Options\Settings-Doctor\Surgical\Reflux)

Menu Bar: Options - DOCTOR SETTINGS - SURGICAL - GENERAL

The General sub-tab (shown in Figure 2-13) allows the user to change the following preferences related to surgery.

- **OZil®/Phaco Sequence** - When an OZil® torsional handpiece is being used, the OZil®/Phaco Sequence setting selection determines whether the torsional or phaco pulse leads the sequence as shown in the illustration in Figure 2-13.
- **Diathermy Control Type** - Allows the user to determine the type of diathermy, Fixed or Proportional, to be used for the current doctor.
- **Surgical Tool Preferences** - Selection determines the default tip selected for the specified handpiece types.
- **Patient Eye Level Offset** - The correct Patient Eye Level Offset setting is necessary to ensure that the displayed console readings reflect the true pressure being delivered to the eye. The Patient Eye Level Offset is the vertical distance from the patient's eye (while lying on the operating table) to the bottom row of connectors on the cassette (see Figure 2-13). This variable distance represents an amount of fluidic pressure that may add or subtract from the pressure displayed on the console. The Patient Eye Level Offset allows the user to enter this distance so the system can compensate for the fluidic pressure variable.
NOTE: On the Constellation® Vision System, the height or position of the infusion bottle does not affect infusion pressure delivered to the eye.
- **Patient Eye Level Offset Units** - Allows the user to determine the units associated with Patient Eye Level Offset values. The unit options are inches (range = 0-39) or centimeters (range = 0-100).

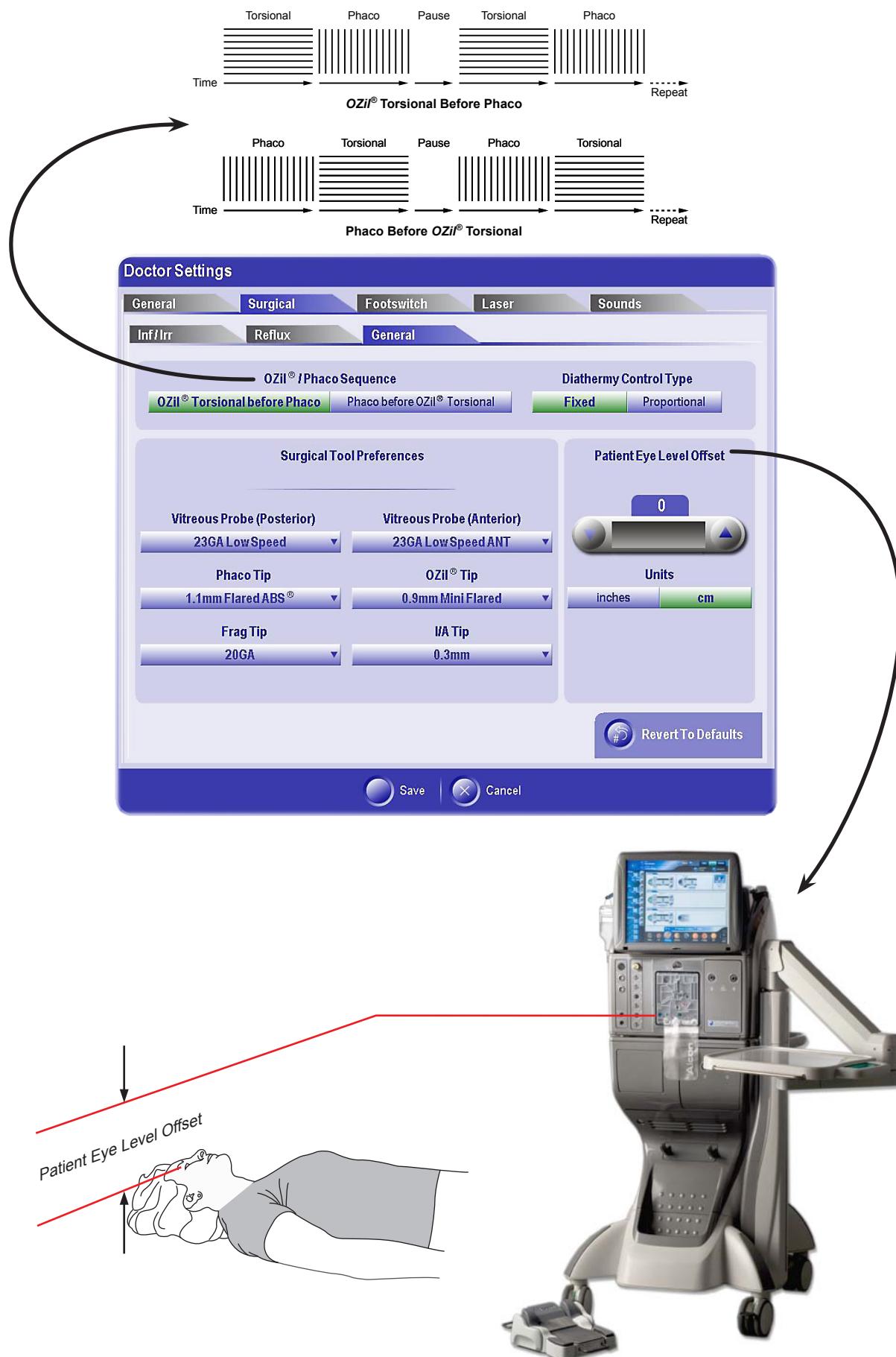


Figure 2-13 The Doctor Settings Popup - Surgical/General Tab
(Options\Settings-Doctor\Surgical\General)

Menu Bar: Options - DOCTOR SETTINGS - FOOTSWITCH

Selecting the Footswitch settings tab from the Doctor Settings screen allows the user to specify functions for footswitch buttons and configure the treadle detents and transitions (see Figures 2-14 through 2-16).



Figure 2-14 Doctor Settings - Footswitch Buttons Screen (Options\Settings-Doctor\Footswitch)

Menu Bar: Options - DOCTOR SETTINGS - FOOTSWITCH BUTTONS

The Footswitch Buttons screen allows the user to change the action of each footswitch button associated with the currently connected surgical footswitch. Each button is labeled with its currently programmed action, and tapping on the label displays a menu that lists the all possible actions for that button in the current mode (see Figure 2-15). Below the footswitch, each mode for the currently selected domain (Posterior or Anterior) is displayed. Table 2-1 lists the default button configuration for each mode and submode. The system is shipped with this default configuration and tapping the Revert to Defaults button returns all modes to the default configuration.

EXAMPLE: Changing the button configuration.

In the Footswitch Buttons Screen, follow the steps below to change button actions.

1. Select the domain: Posterior or Anterior.
2. Select the mode.
3. If applicable, select the submode.
4. Select the label next to the button to be changed. The Footswitch Action Selection popup shown in Figure 2-15 appears with the available selections.

5. Select the desired action from the list shown on the popup. To show additional actions, use the scrollbar to the right of the list.
6. Select whether to apply the change to the current mode/submode or to all modes/submodes for which the footswitch action is valid in the current domain. Selecting cancel will close the popup without changing the button action.

NOTE: When mapping the footswitch button actions to perform diathermy, the horizontal switches do not meet the specification of minimum activation force of 2.25 pounds. It is not in accordance to the governing standards, to have the diathermy activation mapped to the horizontal switches.



Figure 2-15 Footswitch Action Selection Popup

Table 2-1. Default Footswitch Button Actions

| POSTERIOR | | | | | | | |
|--------------|------------|---------------|-----------------|-----------------------------|-----------------------------|--|-------------|
| Mode | Submode | Left Vertical | Left Horizontal | Left Heel | Right Vertical | Right Horizontal | Right Heel |
| Vit | 3D | Diathermy | Reflux | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | Cut Toggle | Next Step |
| | Momentary | Diathermy | Reflux | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | Momentary Vit Cut | Next Step |
| | PropVac | Diathermy | Reflux | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | Cut Toggle | Next Step |
| Frag | 3D | Diathermy | Reflux | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | U/S Toggle | Next Step |
| | Fixed | Diathermy | Reflux | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | US Toggle | Next Step |
| | Linear | Diathermy | Reflux | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | US Toggle | Next Step |
| | Momentary | Diathermy | Reflux | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | Momentary Frag | Next Step |
| Extrusion | -- | Diathermy | Reflux | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | Bimanual OFF: - No Function Bimanual ON: - Momentary Scissors Cut | Next Step |
| Scissors | MultiCut | Diathermy | No Function | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | Close Scissors | Next Step |
| | Prop | Diathermy | No Function | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | No Function | Next Step |
| Forceps | -- | Diathermy | No Function | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | No Function | Next Step |
| VFC | Extract | Diathermy | No Function | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | No Function | Next Step |
| | Inject | Diathermy | Reflux | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | No Function | Next Step |
| Laser | -- | Diathermy | Reflux | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | No Function | Next Step |
| Non Surgical | -- | Diathermy | No Function | No Function | Infusion/FAX Alt/Reg Toggle | No Function | No Function |
| ANTERIOR | | | | | | | |
| Mode | Submode | Left Vertical | Left Horizontal | Left Heel | Right Vertical | Right Horizontal | Right Heel |
| Phaco | 3D | Diathermy | Reflux | Next Submode/ Previous Step | Infusion/FAX Alt/Reg Toggle | Continuous Irrigation Toggle | Next Step |
| | Burst | Diathermy | Reflux | Next Submode/ Previous Step | Irrigation Alt/ Reg Toggle | Continuous Irrigation Toggle | Next Step |
| | Custom | Diathermy | Reflux | Next Submode/ Previous Step | Irrigation Alt/ Reg Toggle | Continuous Irrigation Toggle | Next Step |
| | Pulsed | Diathermy | Reflux | Next Submode/ Previous Step | Irrigation Alt/ Reg Toggle | Continuous Irrigation Toggle | Next Step |
| | Continuous | Diathermy | Reflux | Next Submode/ Previous Step | Irrigation Alt/ Reg Toggle | Continuous Irrigation Toggle | Next Step |
| I/A | -- | Diathermy | Reflux | Next Submode/ Previous Step | Irrigation Alt/ Reg Toggle | Continuous Irrigation Toggle | Next Step |
| Vit | Wet Ant | Diathermy | Reflux | Next Submode/ Previous Step | Irrigation Alt/ Reg Toggle | Cut Toggle | Next Step |
| | Vit Dry | Diathermy | Reflux | Next Submode/ Previous Step | Irrigation Alt/ Reg Toggle | Cut Toggle | Next Step |
| Non Surgical | -- | Diathermy | No Function | No Function | Irrigation Alt/ Reg Toggle | No Function | No Function |

Menu Bar: Options - DOCTOR SETTINGS - FOOTSWITCH TREADLE

The Footswitch Treadle screen shown in Figure 2-16 enables the user to program the treadle vibration, detent firmness, and spans. Depending on the current surgical mode and sub-mode, the treadle has either 2 or 3 functions and the user can program the treadle travel of each position.

- 2-Function Footswitch Transition Position - Sets the transition position (% of treadle travel). Valid range: 20% - 80%
- 3-Function Footswitch Transitions
 - Point 1 - Sets the transition position (% of treadle travel) for transition point 1. Valid range: 15% - 31%
 - Point 2 - Sets the transition position (% of treadle travel) for transition point 2. Valid range: 50% - 100%
- Vibration Enable/Disabled - Allows the user to enable/disable treadle vibration (for both treadle up and treadle down).
- Vibration Frequency - Adjusts the vibration frequency of the treadle when it goes through detents.
- Treadle Firmness - Adjust the firmness of the treadle in a range from 0 to 100%.
- Ramping (%) - These controls set the ramping percentage (%) for each of the modes specified. The ramping percentage determines how quickly each specified 3D mode (Vit 3D, Phaco 3D, or Frag 3D) will ramp up to its start value. For all three modes the valid range is 15% - 90% and the default is 15%.

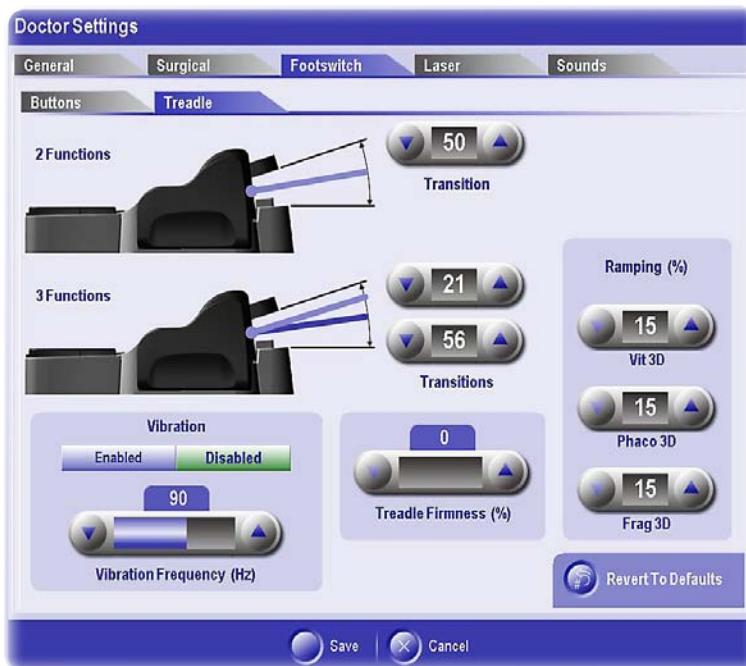


Figure 2-16 Doctor Settings - Footswitch Treadle Screen (Options\Settings-Doctor\Footswitch)

Menu Bar: Options - DOCTOR SETTINGS - LASER

The settings available in the Laser settings screen are for setting the Revert to Standby Timeout and Footswitch Configuration (see Figure 2-17).

Footswitch Configuration

The Footswitch Configuration setting allows the user to enable the side switches to control laser power and transition the system between Ready and Standby. Three options are available as follows:

Power Control and Ready Standby

When this selection is enabled, the user can transition from Standby to Ready by pressing the right side switch longer than the selected (Hold) Duration. A tone sounds when the transition is complete. Similarly, pressing the left side switch longer than the selected (Hold) Duration will transition the system from Ready back to Standby. Pressing the side switches for intervals shorter than the selected (Hold) Duration will increase or decrease treatment laser power.

Power Control Only

This selection allows the side switches to increase (right switch) or decrease (left switch) the treatment laser power.

Standard

This setting disables the side switches entirely. Power control and switching from Standby to Ready mode can only be done from the front panel of the system.



Figure 2-17 Doctor Settings - Laser Screen (Options\Settings-Doctor\Laser)

(Hold) Duration

The (Hold) Duration setting allows the user to select the duration of time that a side switch must be held in order to activate the transition to Ready mode (right switch) or Standby mode (left switch). The range of selection is from 0.5 second to 1.5 seconds in 0.1 second increments.

Revert to Standby Timeout

This setting determines the time period, in minutes, after which the system will revert to the Standby mode of operation due to inactivity. Inactivity is defined as no footswitch activation during the time period. The setting can be adjusted to 2, 5 or 10 minutes.

Aiming Beam On During Standby Mode

This setting determines whether or not the aiming beam is on during Standby Mode. If "No" is selected, the aiming beam will be on in Ready mode only.

Menu Bar: Options - DOCTOR SETTINGS - SOUND SETTINGS

Selecting the Sounds tab displays the screen shown in Figure 2-18. This screen enables the operator to set a volume for all continuous tones as well as voice confirmations for each doctor. In addition to volume level, the operator can also enable/disable a sound, except for the following, which can never be completely turned off:

- Diathermy
- Errors
- Invalid Key
- Infusion Alarm
- Laser
- Phaco Occlusion
- Voice

Each sound can be changed individually or all at once by enabling the Master Override button.



Figure 2-18 Doctor Settings - Sound Screen (Options\Settings-Doctor\Sound)

Menu Bar: Options - SYSTEM SETTINGS

Selecting "System" from the Options menu displays the screen shown in Figure 2-19. This popup screen allows the user to configure settings that are part of the system's normal operation. Once saved by pressing the Save button, the settings become the default when the system is powered up.

SYSTEM SETTINGS - SETTINGS

The Settings screen allows adjustments to the following system parameters:

- **Screen Brightness** - Sets the relative brightness of the touch screen. The allowable range is 1 – 9, with 7 as the default.
- **Language** - Allows the user set the language used for system purposes such as end case reports.
- The **Current Printer** field displays the currently connected printer by host name or IP address. Pressing the Configure Printer button displays the Configure Printer popup where the following selections can be made:
 - *Print Format* - Postscript or PCL
 - *Printer Location*¹ - Auto Search mode displays a list of printers found via UPnP (Universal Plug and Play) protocol (wireless connection). Manual entry mode provides a numeric keypad so the printer's IP address can be directly entered into the system.
- **Auto Gas Fill Purge Cycles** - Allows the user determine the number of purge cycles (1-3) when performing an AGF.

1 If equipped for wireless connection.

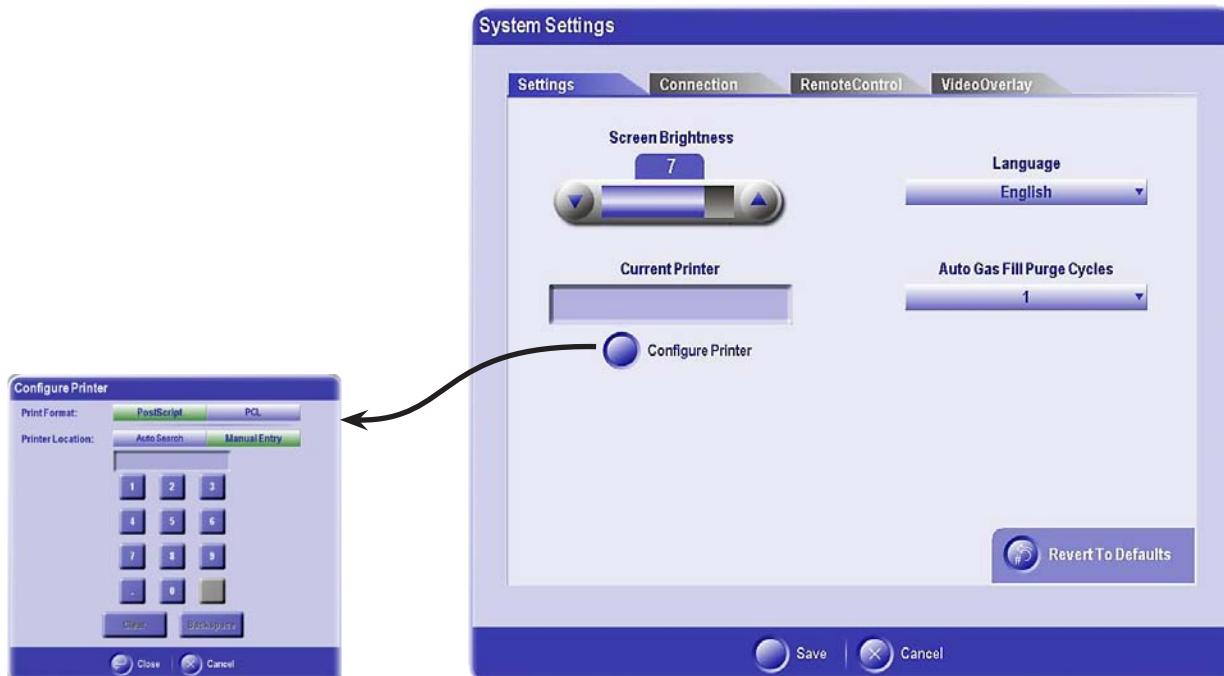


Figure 2-19 System Settings - Settings Screen (Options\Settings-System\Settings)

Menu Bar: Options - SYSTEM SETTINGS - CONNECTION

The Connection screen shown in Figure 2-20 allows the operator to specify network connection information for the instrument to communicate with the Alcon Enterprise Server for remote service activities.

Network Connection¹:

- Configure Button - Pressing the configure button displays the Network Configuration popup where the system displays all wireless networks that have been added to the system. The user can select the desired WiFi profile from the drop-down list or Add, Edit, and Delete profiles as necessary by pressing the associated button.

Required information for configuring a wireless profile includes the 32 character SSID, Authentication, Encryption, and the Passphrase. Pressing the button to the right of the SSID and Passphrase fields will display a keypad for entering the required information.

It is recommended to contact your Information Technology department for assistance in configuring the system for your network.

- Enabled – Indicates the connection is active and available for use.
- Disabled – Connection is not active or not available for use.
- Connection Status - Indicates the connection status of the network, printer, and barcode reader.

eConnectivity¹:

- Enabled – Indicates the connection is active and available for use.
- Disabled – Connection is not active or not available for use.
- Time of Day - Allows selection of time slots in 0.5 hour increments to schedule connection activities.
- Recurring Frequency - Indicates at what frequency a connection will be made:
 - Daily - Every day at the specified time.
 - Weekly – Once a week at the specified time on the specified day of week.
 - Monthly – Once a month on the specified day of month and time of day.

Note: Selecting a day greater than 28 will prevent a connection from occurring in all months.

¹ If equipped for wireless connection.

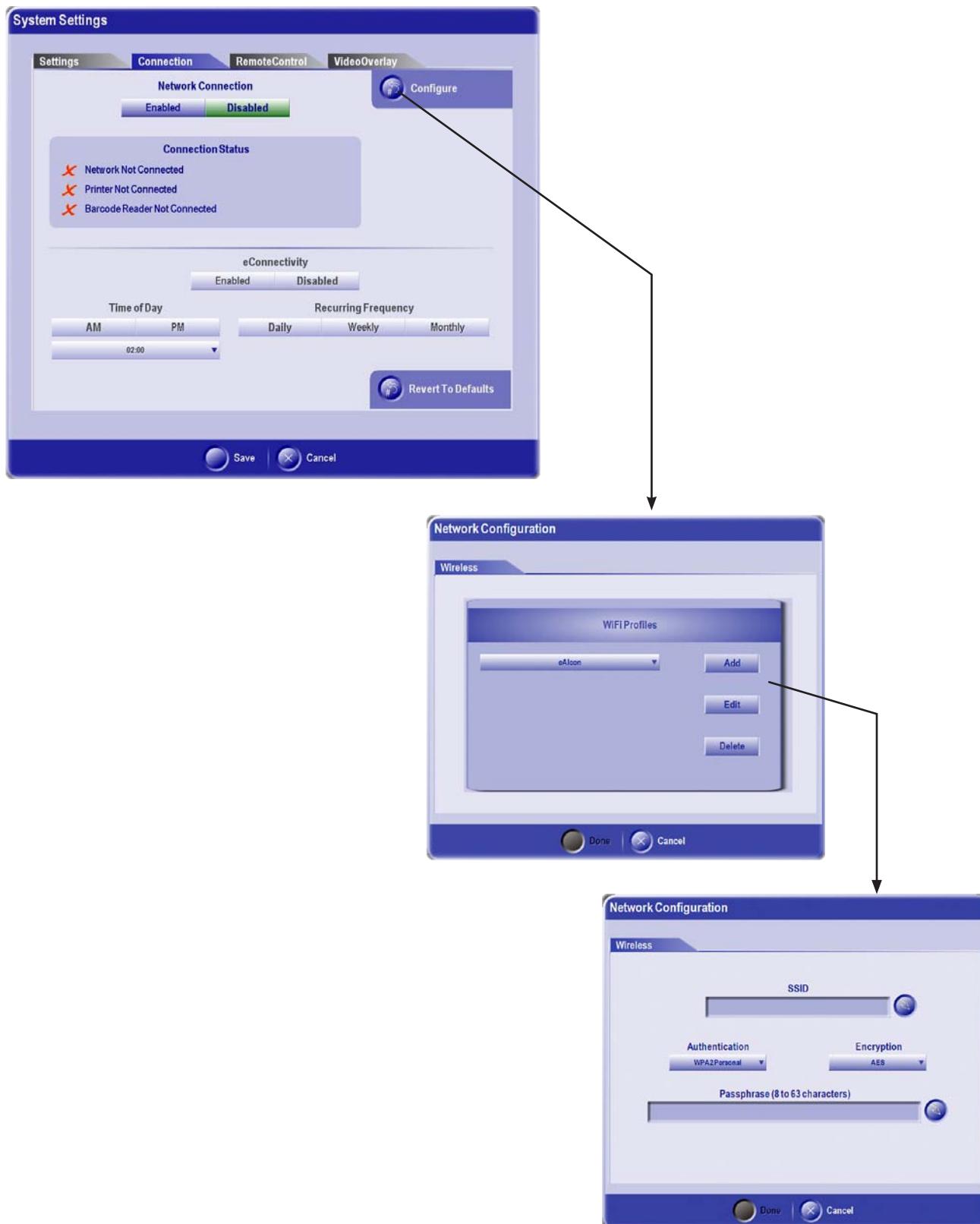


Figure 2-20 System Settings - Connection Screen (Options\Settings-System\Connection)

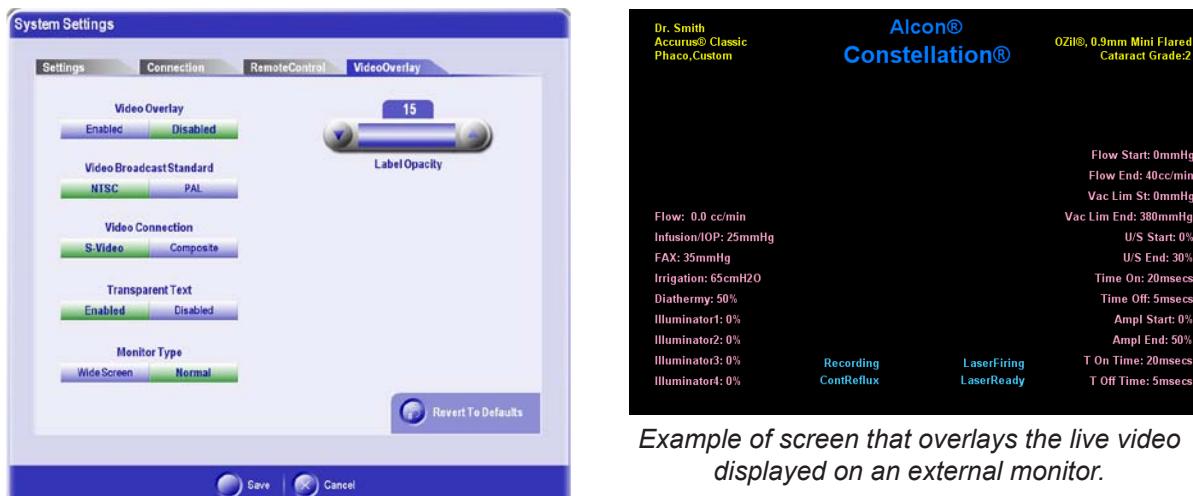
Menu Bar: Options - SYSTEM SETTINGS - REMOTE CONTROL

For information regarding the Remote Control settings, refer to the Remote Control description found earlier in this section.

Menu Bar: Options - SYSTEM SETTINGS - VIDEO OVERLAY**STANDARD DEFINITION VIDEO OVERLAY**

If a Standard Definition Video Overlay card is installed in the system, the Video Overlay setting screen shown in Figure 2-21 provides the settings to enable and setup the Video Overlay system with the *Constellation®* Vision System. See Section Three for a diagram of connections made when connecting a camera, video recorder, and monitor to the system.

- Video Overlay - Allows the user determine whether or not Video Overlay is available. Choices: Enabled or Disabled.
- Video Broadcast - Allows the user determine the video format (NTSC or PAL).
- Video Connection - Allows the user set the type of cable (S-Video or Composite) used to connect to the video recording equipment.
- Label Opacity - Allows the user determine the opacity of the video overlay output (range: 0 – 15).
- Transparent Text - When Transparent Text is enabled, the text shown on the monitor is transparent so the image on the screen can be seen through the text. When disabled, text is displayed on an opaque box to provide greater contrast with the image.
- Monitor Type - Selecting "Wide Screen" adjusts the position of the text/controls as appropriate for a wide screen monitor.



**Figure 2-21 System Settings - Standard Definition Video Overlay Screen
(Options\Settings\System\VideoOverlay)**

HIGH DEFINITION VIDEO OVERLAY

If a High Definition Video Overlay card is installed in the system, the Video Overlay setting screen shown in Figure 2-22 provides the settings to enable and setup the Video Overlay system with the *Constellation®* Vision System. See Section Three for a diagram of connections made when connecting a camera, video recorder, and monitor to the system.

- Video Overlay - Allows the user determine whether or not Video Overlay is available. Choices: Enabled or Disabled.
- Video Connection - Allows the user set the type of cable (S-Video or HDMI) used to connect to the video recording equipment.
- Force English - When enabled, forces the text on the overlay to be displayed in English regardless of the selected doctor or system language.
- Hi-Def Margin - Allows the user to set a margin in percent that defines the area in which the overlay graphics and text should be contained (range is 0.0 to 5.0 percent).

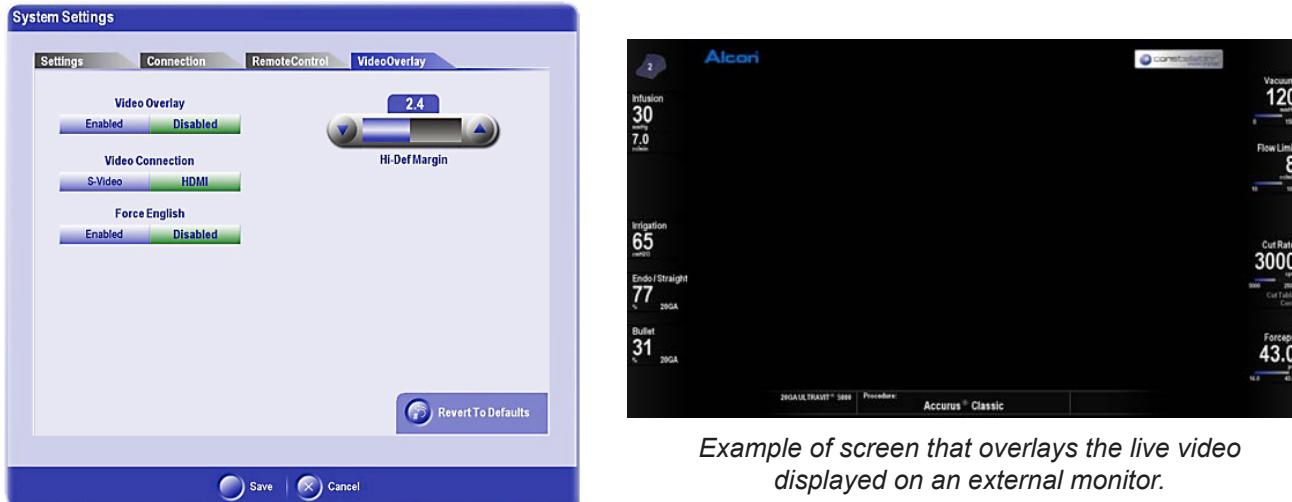


Figure 2-22 System Settings - High Definition Video Overlay Screen (Options\Settings\System\VideoOverlay)

Video Recorder - There are no controls for configuring a Video Recorder other than footswitch mapping that allows the user to start recording and pause recording when the footswitch button is pressed. A Video Camera icon appears in the upper left hand corner of the Main *Constellation®* screen when the recorder is recording. See Section Three for information on connecting the video recorder.

Menu Bar: Options - MAINTENANCE

Maintenance options selectable from the Options popup (see Figure 2-8) include Test Instrument, Clean Cassette, and Field Service.

Test Instrument - Similar to the Start Prime function available on the main screen, pressing this button displays a popup that allows the prime and test of the current setup.

Clean Cassette - The Clean Cassette feature allows the operator to pump the aspirated fluids from the cassette into the drainbag without having to go through to End Case. Pressing the Clean Cassette button causes the process to begin without further user interaction. Once the cleaning process has begun, a popup appears providing feedback on the progress of the cleaning.

Note: This popup also comes up automatically when the user transitions from the Surgery screen area to End Case, if the cassette has been primed and infusion, FAX, and irrigation are not on.

Change Drainbag - Pressing this button displays the "Change Drainbag" popup. Changing the drainbag, then pressing the "Done" button informs the system that a new (empty) drainbag has been installed on the cassette.

Field Service - Used by the trained Alcon Field Engineer to access system information that will aid in the servicing of the instrument. A pass code is required to access this information.

Menu Bar: Options - EXTRAS

Extras options, selectable from the Options popup, include Auto Gas Fill, Consumables, and Update.

Menu Bar: Options - EXTRAS - AUTO GAS FILL

The Auto Gas Fill popup shown in Figure 2-23 steps the operator through the process of filling syringes with the specified gas (either C3F8 or SF6). In Surgery Mode, the operator can optionally use the Auto Gas Fill button within the surgery header to launch this popup.

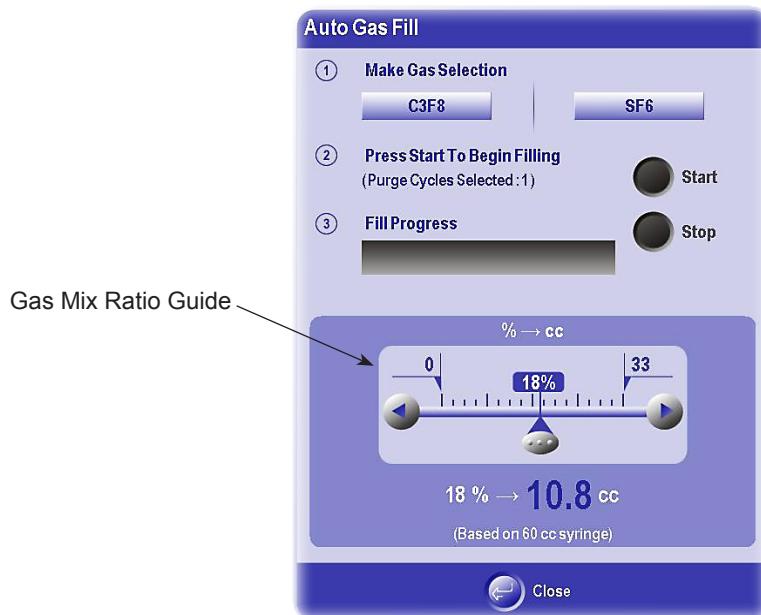


Figure 2-23 Auto Gas Fill Popup (Options\Settings\System\Extras\Auto Gas Fill)

WARNING!

Be sure to connect gas bottles to the proper connectors. Bottle valves, tubing, and connectors are color coded as follows: C3F8 = Red, SF6 = Blue.

1. Make Gas Selection: C3F8 or SF6 - Gas bottle(s) are connected to system through the mechanical regulator valve located at the back of the console.
2. Press Start To Begin Filling - Press the “Start” button to start filling the syringe with the selected gas type. The button is initially disabled and is only enabled during the time period between a gas selection and the commencement of a fill operation.
3. Fill Progress - Displays the status of the fill process. After the process is complete, the number of purge cycles is displayed. The number of purge cycles is set in the System Setting screen (Options\Settings\System) and has a range from 1 to 3 cycles. The number of purge cycles affects the gas concentration percentage in the Auto Gas Fill syringe according to the following table.

| Number of Purge Cycles | Minimum Gas Concentration, [G]min | |
|------------------------|-----------------------------------|-------------------------------|
| | SF ₆ | C ₃ F ₈ |
| 1 | 97.3% | 97.1% |
| 2 | 99.4% | 99.2% |
| 3 | 99.8% | 99.7% |

The status bar graphically illustrates the progress of the fill operation. If necessary, press the Stop button to stop filling the syringe in the middle of a fill cycle. The button is initially disabled and is only enabled during a fill operation.

The Gas Mix Ratio Guide is a tool to assist the user in calculating the syringe volume adjustments required in order to achieve the desired mixture. **NOTE: Adjusting the Gas Mix Ratio Guide does not automatically fill the syringe to the desired mixture. The user must manually move the plunger to make the gas volume adjustment in the syringe after detaching the syringe assembly from the console.**

To achieve a specific gas/air mix ratio (after the system has purged then filled the syringe to 20cc of gas), use the Gas Mix Ratio Guide as follows:

1. Move the slider on the guide to the desired percent of gas mixture. The guide displays the syringe reading that the plunger must be moved to in order to achieve the displayed percentage of gas in the syringe (18% -> 10.8 cc in Figure 2-23).
2. For an 18% gas mixture, push the plunger from 20 cc to 10.8 cc. Then pull the plunger out to 60 cc. The resulting mixture will be 18% of the selected gas.

Menu Bar: Options - EXTRAS - CONSUMABLES

This button and the Consumables button displayed on the Setup screen (Figure 2-7) both display the Consumables popup when pressed. The Consumables popup is described later in this section of the manual (see Figure 2-50).

Menu Bar: Options - EXTRAS - UPDATE

This feature is reserved for future enhancements.

Menu Bar: Options - INFO

Info options selectable from the Options popup (see Figure 2-8) include View/Copy/ Delete, Event Log, and About (system information).

Menu Bar: Options - INFO - VIEW/COPY/DELETE

The View/Copy/Delete screen shown in Figure 2-24 allows the user to perform data management related tasks including:

- Copy data from a source memory device to a destination memory device. This is essential to backup data or to move settings to another system.
- Rename selected data items including doctor names, procedure names, and surgical end case names.
- Delete selected data items including custom doctors and surgical end cases.
- View selected data items including doctor settings and surgical end cases.
- Print selected data items including doctor settings and surgical cases.

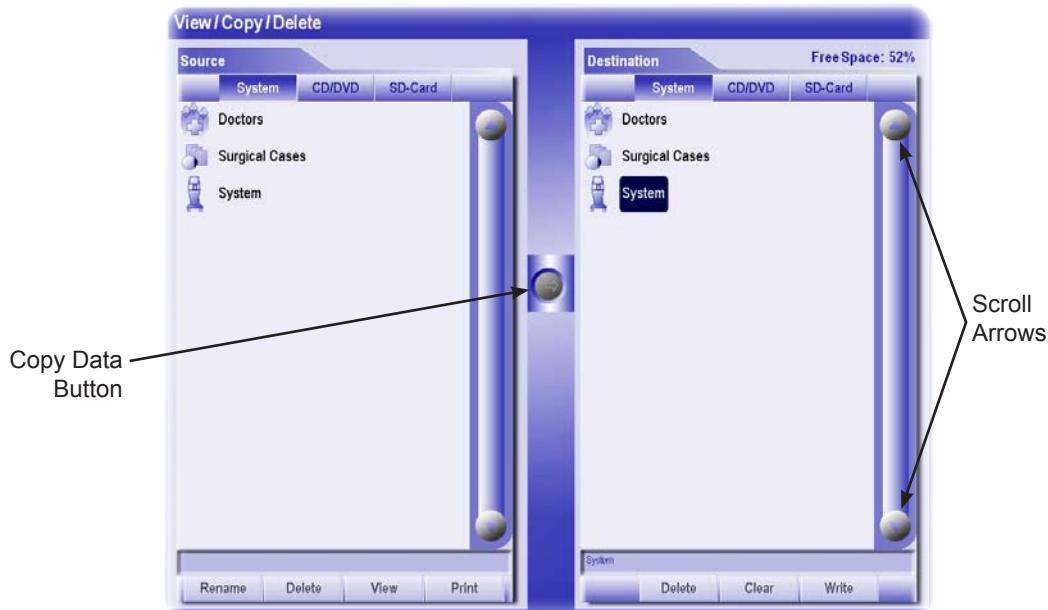


Figure 2-24 View/Copy/Delete Screen (Options\Settings-System\Info)

The Source tab of this screen shows information about the media used as the source of a data management or copy operation. The Destination section shows the information for the media used as the targeted location to move data to. Each section shows the media options available to manage data. To select a media option, simply press the selection and the display will show the current contents in a hierachal structure. The media options are:

- System – refers to the local *Constellation®* Vision System file.
- CD/DVD – Removable media.
- SD-Card – Removable Media card.

If CD/DVD or SD-Card are selected and neither is inserted into the system, a popup will appear indicating that no media has been detected and prompting the user to insert a valid media.

At the top of each section, the status of the selected media is displayed.

- xx% Free - Percent of total space available for storage. In Figure 2-24, the display indicates that 52% of the system data storage media is available for additional data.
- Locked – Indicates that a read-only CD/DVD is inserted into the system.

The Data Structure Tree displayed after media selection allows the user to rename, delete, view, or print the selected item. If any of these operations can be performed on the item, the associated button, located at the bottom of the screen, will have a dark background color. There are items such as "Default Doctor" that cannot be renamed or deleted.

If an item has additional items below it in the structure, selecting it will expand the structure and selecting again will collapse the structure. If the structure tree expands beyond the screen limits, scroll arrow are available in each corner to scroll to hidden parts of the structure.

To Rename an item:

1. Press the item to select it then press the Rename button. Only doctor names, procedure names, and surgical end case data items can be renamed.
2. When the Keyboard popup appears, press the Backspace key or the Clear key to delete the current name then type in the new name.
3. Press Close to save the name and return to the previous screen. Pressing Cancel will close the keyboard popup without saving the changes.

To Delete an item:

1. Press the item to select it then press the Delete button. Some items cannot be deleted such as the Default Doctor.
2. When the confirmation popup appears, press Yes confirm or No to cancel the delete action.

VIEWING AND PRINTING DATA

Doctor Settings and Surgical end case data items can be viewed and printed. To view the data associated with one of these items, select the item then press the View button. A detailed view of the item is displayed such as the sample shown in Figure 2-25. The Page arrow buttons are used to navigate to the previous page and next page. Pressing the close button will close the View screen and return to the View/Copy/Delete screen.

To print a detailed report of an item, select the item then press the Print button. A popup will be displayed indicating that the report is being sent to the printer connected to the system. Printouts of data are identical to the layout of a reports displayed using the View button.

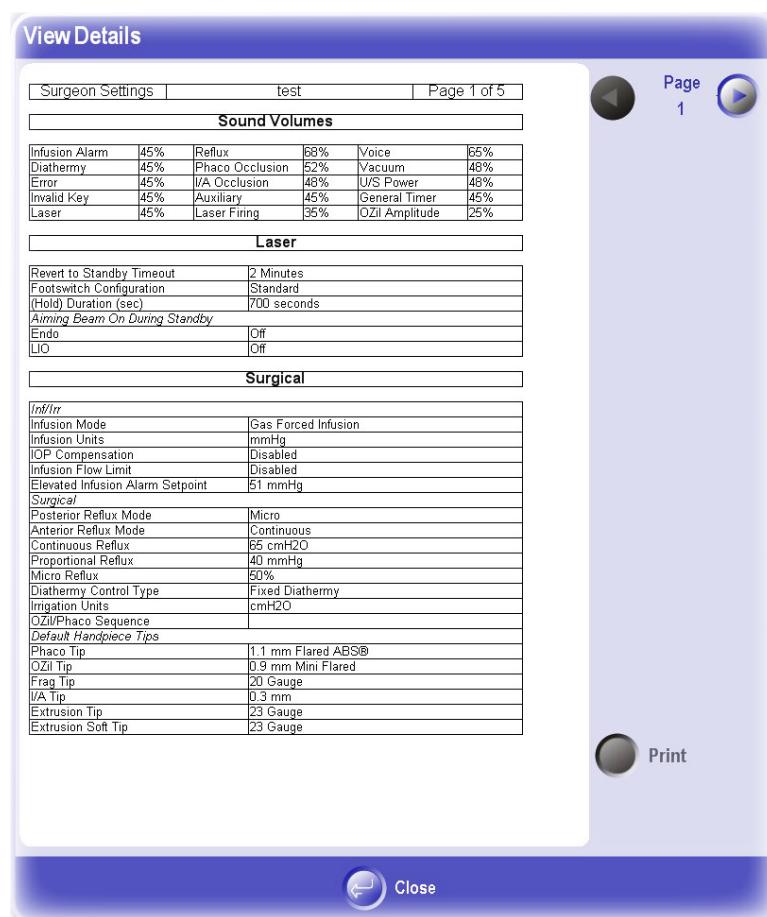


Figure 2-25 Sample View of a Doctor Settings Report

COPYING DATA

Copying data between the source device and destination device is performed by first selecting a source data item and then pressing the Copy Data button. When pressed, the source data item is copied to the destination device at the same location defined by the source data item (i.e., the hierarchy is preserved).

To finish the process of copying data to a SD Card or a CD/DVD, the Write button must be pressed. If there is not enough space on the remote disk, you will be prompted to remove some items and try again.

If an attempt is made to copy a file that already exists on the destination device, a popup will be displayed indicating the file already exists and the following options are available:

- Overwrite - Replaces the destination file with the new source file.
- Copy - Selecting Copy opens the keyboard popup so the user can rename the file. The old file is not overwritten in this case.
- Cancel - Stops the Copy process with no changes.
- Skip - This button is displayed only when copying multiple doctors that have already been saved to the destination. Pressing the Skip button skips the current doctor listed in the upper left corner of the popup and moves to the next doctor.

Menu Bar: Options - INFO - EVENT LOG

Figure 2-26 shows the Event Log where system messages are displayed that have occurred during the previous seven days. The list can be filtered to display a specific type of message by pressing the associated button on the right side of the screen.

To view the Event Log:

1. Press Options from the Menu bar.
2. Under the Info tab press "Event Log." The default view is displayed showing a list of all faults, errors, advisories, and information messages. Pressing the associated button will hide that type of message on the list. If the list goes beyond the viewable area, a scroll bar is provided to move through the list.
3. To view the details of a specific message, select the message on the list, then press View Details. A pop up appears with a description of the message and the date and time it occurred.
4. Press Close to go back to the previous screen.

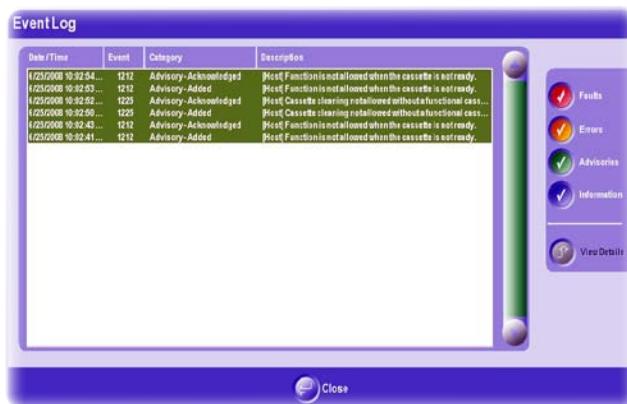


Figure 2-26 Event Log (Options\Info)

Menu Bar: Options - INFO - ABOUT

The "About Constellation" popup (shown in Figure 2-27) displays the software configuration information for the Host and sub modules:

All Languages installed in the system are also listed here.

Patent information for the *Constellation®* Vision System is displayed by pressing the Patents button.



Figure 2-27 "About Constellation" (Options\Info)

Menu Bar - Screen Navigation

The *Constellation®* Vision System operates in one of three “System States”:

- Setup – Contains the screens for setting up the system in preparation for surgery.
- Surgery – Contains the screens for controlling and viewing surgical functions (vacuum, ultrasound, etc.)
- End Case – Contains the screens for completing and reporting a case.

Navigation between the System States is associated with certain rules as stated in the following table:

| From | To | Rules |
|----------|----------|--|
| Setup | Surgery | None |
| Surgery | End Case | Going from Surgery to End Case will “close” the case. This includes saving case related information. To avoid accidentally closing a case, the user is asked to confirm the transition. |
| End Case | Setup | None |
| Surgery | Setup | The intended use of the system is to always end each case by going to End Case. However, the user is not forced to go through End Case to start a new case. In order for the system to know when a case ends without going through End Case, a pop-up is displayed when navigating from Surgery to Setup. This popup asks the user whether he wants to start a new case (or just go back to Setup for the current case). |
| End Case | Surgery | Not possible |
| Setup | End Case | Going from Setup to End Case will close the case. This includes saving case related information. To avoid accidentally closing a case, the system prompts the user to confirm the transition. |

GLOBAL CONTROLS

The Globals area of the screen allows the user to control certain functions that are available in any of the system states (Setup, Surgery, and End Case). Global functions can typically be turned on or off independently of other surgical functions (vacuum, U/S power, etc.), although in some cases global functions are required to be on in order to perform surgery. When a global function is on, the On/Off button is green and the background becomes lighter in color.

Infusion Global Control

The Infusion global control (see Figure 2-28) is a dual function that controls both infusion and IOP Compensation (if enabled in the Options/Doctor/Surgical popup).

The infusion global control allows the user to:

- Turn infusion On/Off.
- Adjust infusion setpoints.
- Enable IOP Compensation mode (secondary function buttons).
- Display more information that allows the user to easily make detailed changes to the infusion settings.

The Elevated Infusion Timer is displayed when infusion rises above the setpoint entered in the Surgical Options popup (Options/Doctor/Surgical). It displays the amount of time infusion has been elevated above the setpoint.

WARNING!

The closed loop system that adjusts IOP cannot replace the standard of care in judging IOP intraoperatively. The surgeon must continue the common practice of informally judging IOP using the following:

- Finger palpation on the globe
- Tactile feedback of the surgical instruments (eye wall deformation with manipulation of instruments)
- Retinal vessel perfusion/pulsations
- Presence of corneal edema

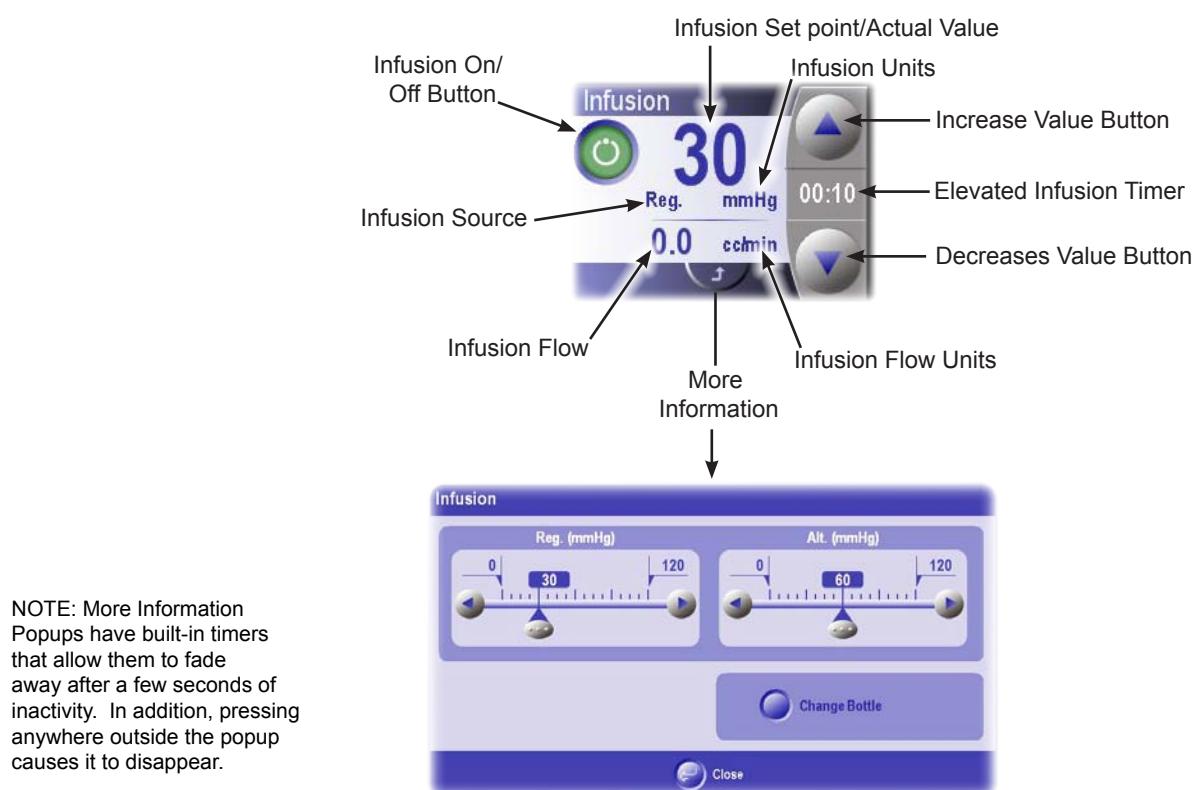
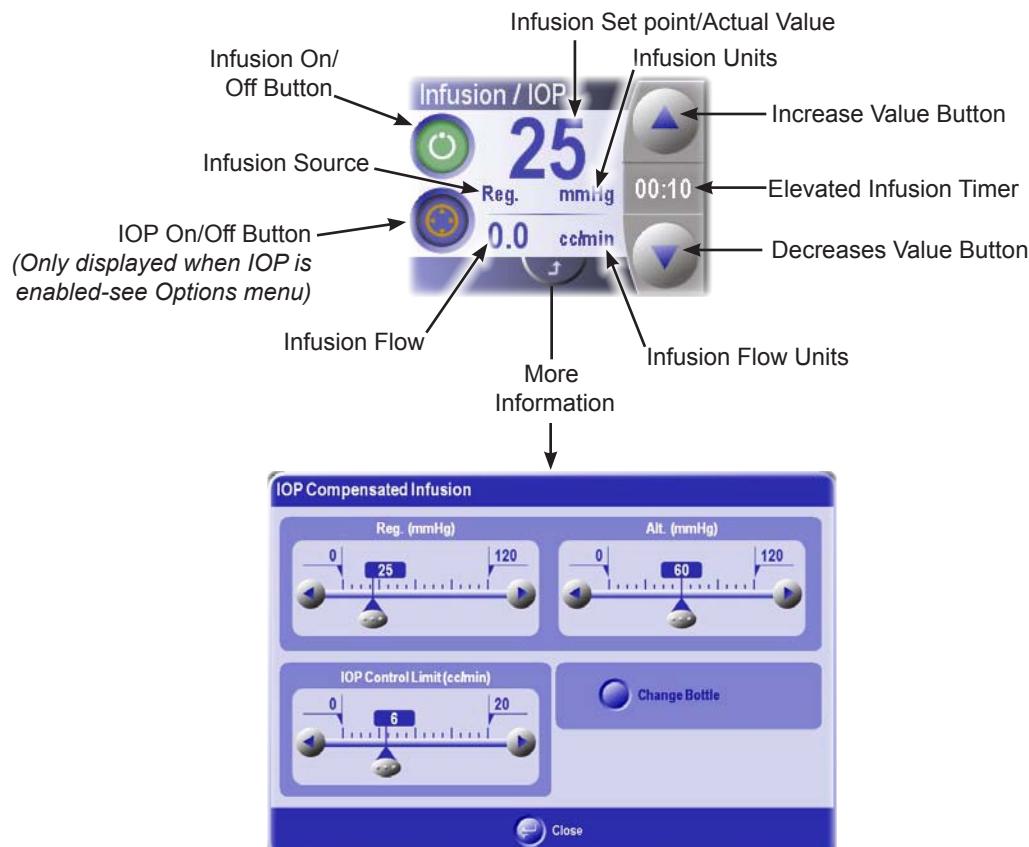
If the surgeon believes the IOP (using the techniques above) is not responding to the system settings and is dangerously high, this may represent a system failure. The surgeon can do one or more of the following as they deem appropriate in this situation (with care to avoid sudden hypotony):

- Close the infusion stop-cock
- Pinch the infusion line
- Remove the infusion line from the sclerotomy

The More Information popup for Infusion allows the user to quickly set values for its two different set points:

- Regular infusion - Infusion value the system will go to upon entering infusion mode.
- Alternate infusion - Infusion value the system will go to when the footswitch button is pressed that is assigned the "InfusionFaxAltRegularToggle" action.

Additionally, the popup contains a Change Bottle button that will open the Fluid Container Setup popup discussed later in this section.

INFUSION GLOBAL CONTROL (IOP NOT ENABLED)**INFUSION GLOBAL CONTROL (IOP ENABLED)****Figure 2-28 Infusion Global Control**

Fluid/Air Exchange (FAX) Global Control

The FAX global control turns Fluid/Air Exchange on/off and adjusts the setpoints.

The More Information popup is designed to enable the user to quickly set values for its two setpoints:

- Regular FAX - Value the system will go to upon entering FAX mode.
- Alternate FAX - Value the system will go to when the footswitch button is pressed that is assigned the "InfusionFax/AltRegularToggle" action.

The Elevated Infusion Timer is displayed when infusion rises above the setpoint entered in the Surgical Options popup (Options/Doctor/Surgical). It displays the amount of time infusion has been elevated above the setpoint.

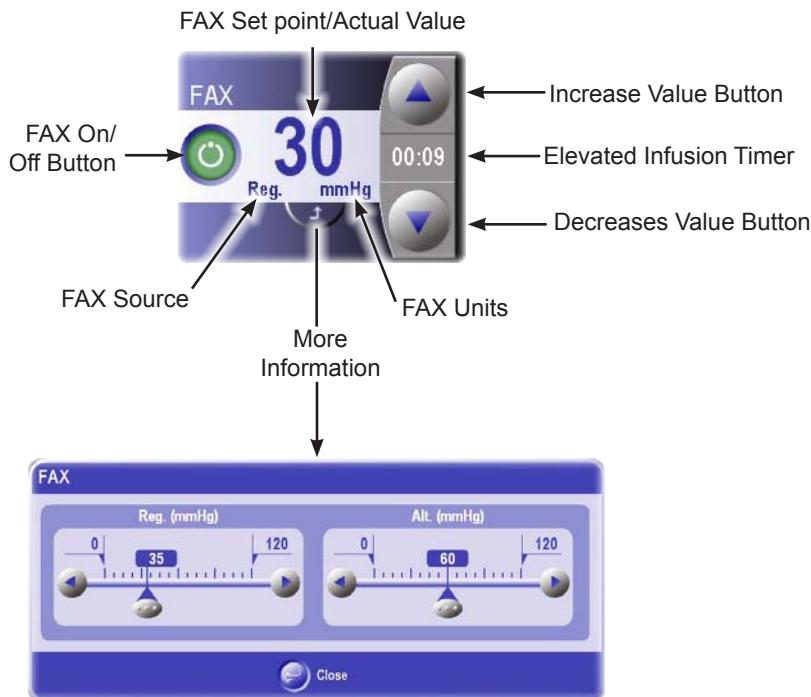


Figure 2-29 FAX Global Control

Irrigation Global Control

The Irrigation global control turns Irrigation On/Off and adjusts setpoints. The More Information popup for Irrigation allows the user to quickly set values for its two different set points using the slider controls:

- Regular Irrigation - Irrigation value the system will go to upon entering Irrigation mode.
- Alternate Irrigation - Irrigation value the system will go to when the footswitch button is pressed that is assigned the "Irrigation Alt/Reg Toggle" action.

Additionally, the popup contains a change bottle button that will open the Fluid Container Setup popup discussed later in this section.

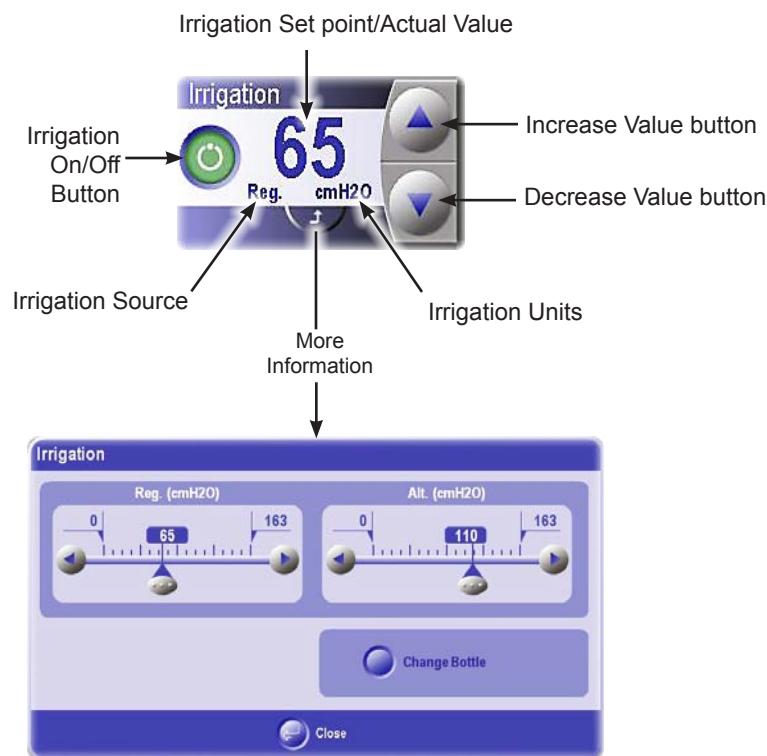


Figure 2-30 Irrigation Global Control

Diathermy Global Control

Diathermy Global displays the diathermy mode (fixed/proportional), displays the setpoint/actual value, and adjusts setpoints. The mode can be selected from the More Information dialog by selecting either Fixed or Proportional. Selecting Fixed diathermy provides a fixed percentage of diathermy power when the mapped footswitch button is pressed. Proportional diathermy increases the diathermy power in proportion to the distance the footswitch treadle is depressed. In Proportional Diathermy mode, pressing the mapped footswitch button displays the Proportional Diathermy progression box. When the progression box is displayed, depressing the treadle increases the diathermy power.

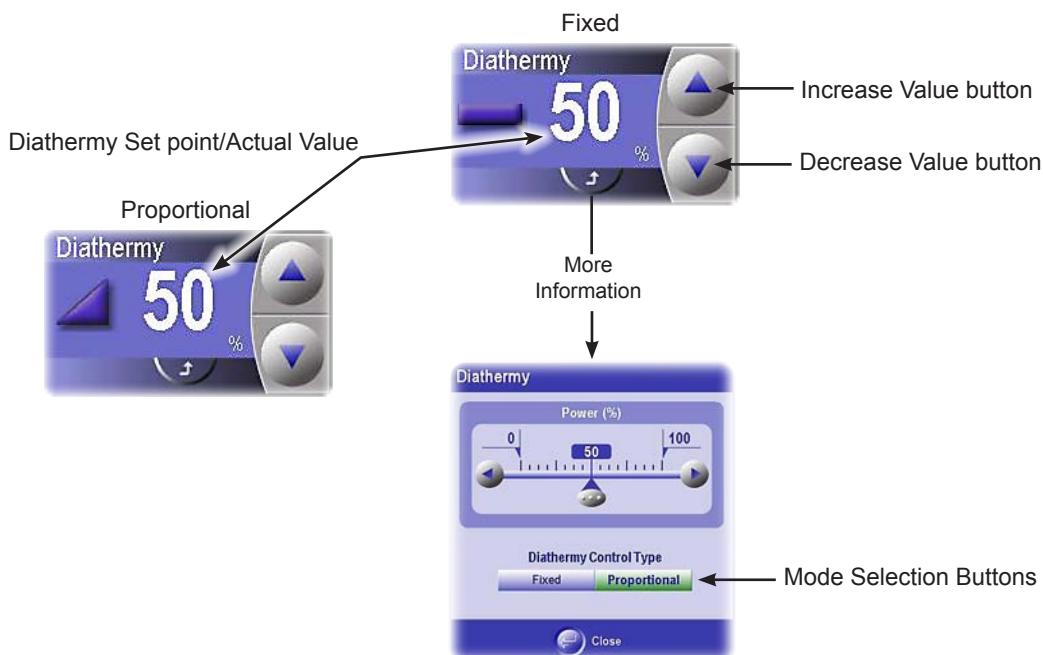


Figure 2-31 Diathermy Global Control

Illuminator Global Control

The Illuminator Global control turns up to four illuminators on/off and adjusts setpoints. The bulb usage indicator ring light that surrounds the On/Off button, shows how long the illuminator bulb has been in use. This indicator ring has three indication colors:

- Green: 0 to 199 hours
- Yellow: 200 to 399 hours
- Orange: greater than or equal to 400 hours

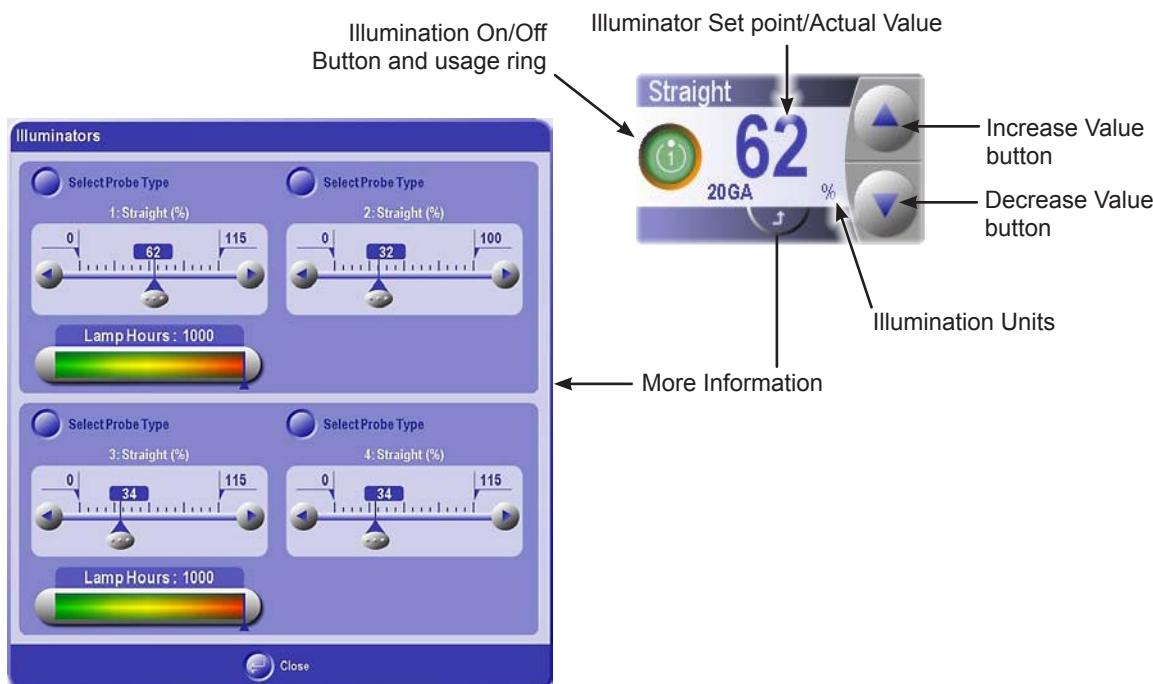


Figure 2-32 Illuminator Global Control

The More Information popup for the Illuminators allows the user to set values for the setpoints and confirm lamp hours. The system automatically sets the upper limit for each probe by reading the RFID tag for the probe. The surgeon has the ability to override this automatic upper limit for luminous flux, but if he does so, a pop-up will appear that will alert him to the consequences of doing so (i.e. reduction in exposure time to give the equivalent aphakic energy exposure). If four illuminators are available, the More Information popup allows for the setup of all four illuminators in one screen.

WARNING!

To minimize hazardous light exposure, operate light source at lowest intensity setting consistent with adequate visibility of the surgical area.

CAUTION

Avoid prolonged operation of any fiber optic endoilluminator probe in air. This may result in tip deformation of plastic fiber optic endoilluminator probes. This system will display the following advisory to indicate this condition: "Further increasing the output level in air can damage fiber tips. Would you like to continue?" Avoid placing illuminated fiber optic endoilluminator probes in contact with materials such as sterile drapes.

NOTE: Light output from a new lamp may greatly exceed the output from the old lamp. Adjust output to lower settings after installing a new lamp.

SYSTEM STATE AREA

The System State area provides specific information on one of the following available states : Setup, Surgery, or End Case. These states are selected by pressing the associated tab in the menu bar.

Setup

System setup can be accomplished using the seven setup panels shown in Figure 2-33, the Detailed Setup screens, or a combination of both. The Detailed Setup screens are explained later in this section and include much more detailed information than the Setup panels. In both the Setup panels and Detailed Setup screens the user can perform the following actions:

- View available surgical tools and consumables options.
- Connect the surgical tools and options essential for the upcoming operation.
- Prime/Test the surgical tools before commencing surgery.

Basic Setup

The basic setup uses the seven setup panels shown in Figure 2-33. These panels are always displayed in the system state area during setup. Experienced *Constellation®* Vision System users will normally use these panels to quickly setup the system. If desired, the detailed setup screens can be displayed by pressing the Setup button in the Menu Bar or pressing the More Information button  on any of the seven panels.

Note: Using the barcode scanner to scan a pack automatically sets up these panels for the accessories in that pack.

The seven panels displayed on the Setup Screen are:

- Fluidics
- Accessories
- Status
- Probe
- Illuminators
- Handpiece
- Lasers



Figure 2-33 The System State Area of the Main Screen

Basic Setup: The Fluidics Setup Panel

The Fluidics Setup panel allows the user to view and update setup information relating to the cassette, fluid container, and associated surgical tools. Figure 2-34 shows the panel first without a cassette inserted then with a cassette inserted and primed.

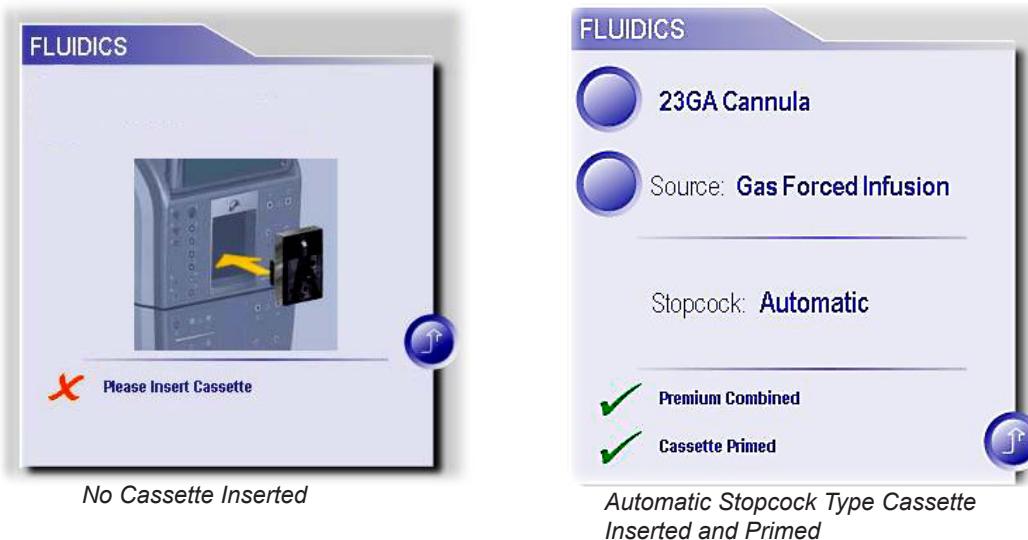


Figure 2-34 The Fluidics Setup Panels

Pressing the option buttons on these panels displays the following selections:

Cannula Button:

- 20 GA Cannula
- 23 GA Cannula
- 25 GA Cannula
- 27 GA Cannula

Source Button (Infusion/Irrigation):

- Gas Forced Infusion
- Power Pole
- Gravity

Infusion Tubing:

This information is displayed only when the cassette is inserted and shows the compatible infusion tubing (i.e., stopcock type: automatic or manual) for the inserted cassette.

- Automatic Stopcock – User does not have to operate the stopcock when switching between air and fluid.
- Manual Stopcock – User has to turn the switch on the tubing set to alternate between air and fluid flow.

Pressing the More Information button opens the detailed setup popup that is covered later in this section.

Basic Setup: The Probe Setup Panel

This panel shows setup information related to the vitreous probe selection. Figure 2-35 shows the Probe Setup Panel:

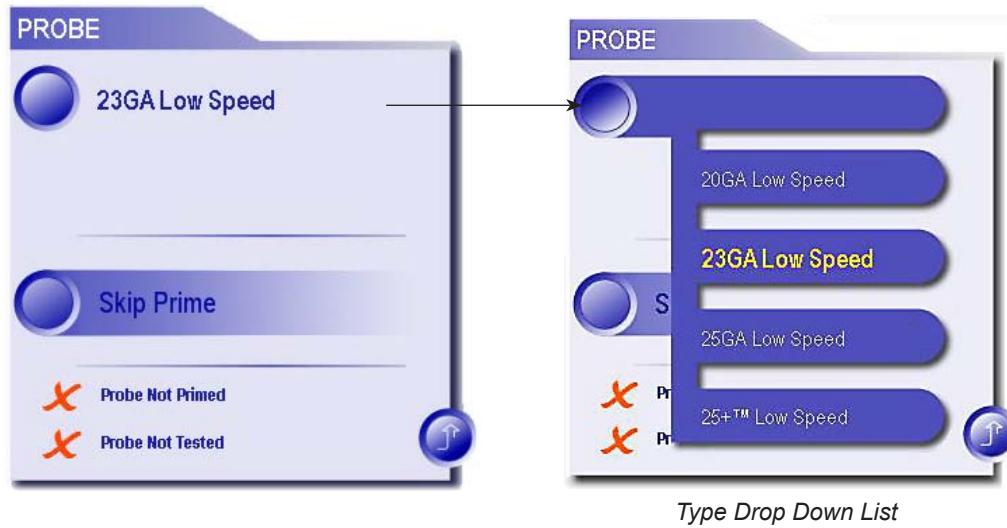


Figure 2-35 The Probe Setup Panel

Type Button - Pressing this button displays the drop down list that has the various options for vitreous probe selection (see second screen in Figure 2-35). Pressing one of the selections makes that probe type the active selection.

When the system detects that a probe has been connected, the probe type is automatically selected and the “connected” icon  appears next to the selection list.

Skip Prime Option Button - Selecting this option tells the system to skip priming the selected vitreous probe. This button is a toggle switch that displays a check mark in the center of the button when active. When the check mark is present, the system will not prime nor tune the vitreous probe in the next Prime/Tune request.

More Information Button  - Pressing the More Information button opens the detailed setup popup that is covered later in this section.

Probe status is displayed at the bottom of the setup panel and indicates whether the probe has been primed and tested. A “√” indicates that the priming and/or testing have been completed, while an “X” indicates that they have not.

Basic Setup: The Handpiece Setup Panel

This panel shows setup information related to handpiece selections. Figure 2-36 shows the Handpiece Setup Panel.



Figure 2-36 The Handpiece Setup Panel

Type Button - Pressing the Type button on the panel displays the list of handpieces that may be used with the system. When the system detects that the user has plugged in the handpiece, the handpiece name is automatically selected and the “connected” icon  appears next to the selection list.

The following handpiece types are selectable from the drop list:

- Extrusion
- Extrusion SoftTip
- Frag* (Fragmentation)
- I/A (Irrigation/Aspiration)
- *OZil®** Handpiece
- Phaco*
- None

Handpieces that are marked with an asterisk (*) are automatically detected by the system.

Tip Button - Pressing the Tip button displays the tips that the operator can choose for the currently selected/inserted handpiece. The tip selection button is hidden if the currently selected handpiece is “None”

More Information Button  - Pressing the More Information button opens the detailed setup popup that is covered later in this section.

Handpiece status is displayed at the bottom of the setup panel and indicates whether the probe has been primed and/or tuned. A “√” indicates that priming and/or tuning have been completed, while an “X” indicates that they have not.

Basic Setup: The Accessories Setup Panel

Figure 2-37 shows the Accessories Setup Panel. On the panel, pressing a button next to an accessory will display a popup with specific selections for that accessory. The following accessories selections are available:

- Auto Gas Fill (AGF)
- VFC (Viscous Fluid Control)
- Forceps
- Scissors
- Diathermy



Figure 2-37 The Accessories Setup Panel

Auto Gas Filling (AGF) - Pressing this button illuminates the ring on the AGF port on the front panel. When the system detects connection of the AGF syringe assembly, the connected icon  appears next to Auto Gas Fill.

VFC (Viscous Fluid Control) - Pressing this button illuminates the ring on the VFC port on the front panel. When the system detects connection of the VFC tubing set, the connected icon  appears next to VFC.

Forceps - When the system detects that the user has plugged in the Forceps handpiece the connected icon  appears next to the selection list. In addition, when the operator presses this button, the system illuminates the LED on the forceps port on the front panel.

Scissors - Pressing the button next to Scissors shows the following scissors options:

- Proportional
- Multicut

When the system detects that the user has plugged in the Scissors handpiece, the scissors type is automatically selected and the connected icon  appears next to the selection list. In addition, when the user selects a scissor type from this list, the system illuminates the LED on the scissors port on the front panel.

Diathermy - Pressing this button illuminates the ring on the Diathermy port on the front panel.

More Information Button  - Pressing the More Information button opens the detailed setup popup that is covered later in this section.

Basic Setup: Illuminators Setup Panel

This panel shows setup information related to illuminator selections. Figure 2-38 shows the Illuminators Setup Panel.

Illuminator Ports - Pressing any one of the illuminator ports allows the user to select between a straight, wide angled, or chandelier endoilluminator probe. In addition, when the user makes a selection from the drop list, the system illuminates the ring on the associated illuminator port on the front panel. When the system detects connection of an endoilluminator probe on a port, the "connected" icon appears next to that port on the selection list and the operator will not be able to select another probe type from the touchscreen for that port (the selection list will be locked).

If a non-RFID probe is inserted into an illuminator port, the system displays "Unrecognized" in the Setup panel and the Illumination Type Selection popup displays a list of possible selections.

More Information Button  - Pressing the More Information button opens the detailed setup popup that is covered later in this section.



Figure 2-38
The Illuminator Setup Panel

Basic Setup: Laser Setup Panel

The Lasers Setup panel shown in Figure 2-39 displays setup information related to laser probes.

Laser Port 1 and 2 Probe Selection - Pressing the Laser Port 1 or 2 button displays a list of selectable probe types:

- Endo
- LIO (Laser Indirect Ophthalmoscope)

When one of the buttons is pressed, the system also illuminates the ring on the associated laser port on the front panel. When the system detects the connection of a laser probe on a port, the connected icon  appears next to the selection list, and the user will not be able to select another probe from the touchscreen for this port (the selection list will be locked).

If a non-RFID probe is inserted into a laser port, the system displays "Unrecognized" in the Setup panel. Pressing "Unrecognized" displays a list of possible selections.

More Information Button  - Pressing the More Information button opens the detailed setup popup that is covered later in this section.



Figure 2-39 The Lasers Setup Panel

Basic Setup: Status Setup Panel

The Status Setup panel shown in Figure 2-40 displays the inlet pressure and gives status of its current state:

- Green background: inlet pressure within optimal range
- Yellow background: inlet pressure acceptable but with potentially reduced performance
- Orange background: inlet pressure out of range

More Information Button  - Pressing the More Information button opens the popup shown in Figure 2-40 that provides additional details on the inlet pressure.

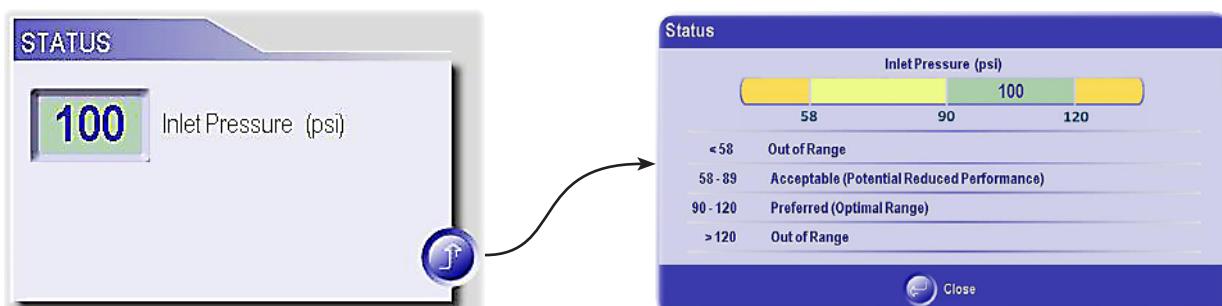


Figure 2-40 The Status Setup Panel

Detailed Setup

The Detailed Setup screens are displayed by pressing the Setup button in the Menu Bar or pressing the More Information button  on any of the seven setup panels discussed previously. Figure 2-41 shows the Fluidics Detailed Setup screen. On the left side of the screen are seven selection controls that, when pressed, display the detailed information related to that control.

The seven selections on the Detailed Setup screen are:

- Fluidics
- Probe
- Handpiece
- Accessories
- Illuminators
- Lasers
- Priming Tray

Pressing a selection presents a graphical display of the step required to successfully setup that selection. The Help button at the bottom of the setup screen allows the user to access a video demonstration of the setup process (see Video Help at the end of the Detailed Setup section).

Connection Help - Pressing a highlighted area on the *Constellation®* system shown below the selection area displays a detailed view of the connections for each the following areas on the front panel: electrical/pneumatic, cassette, illuminators, and lasers.

Start Prime Button - The Start Prime button at the bottom of each detailed setup screen enables the user to initiate the priming process (same function as the Start Prime button located in the menu bar of the setup screen). When the user presses this button, the detailed setup dialog closes and the system initiates the Priming/Testing sequence and displays the Prime Test status dialog.



- **Push Prime** - Push prime is the system default when a new cassette is inserted into the system at the beginning of a surgical case. During push prime, irrigation solution is "pushed" through both the irrigation and aspiration lines. When push prime is active, the Start Prime button appears with no icon as shown at left.



- **Suction Prime** - Suction prime is used in the event an accessory must be re-primed after the surgical case has started. In this situation, the handpiece must be inserted into a container of sterile solution, and priming is accomplished through suction (aspiration) pulling the solution from the container. When suction prime is active, the Start Prime button appears with an icon as shown at left.

Detailed Setup: Fluidics

The Fluidics setup panel shown in Figure 2-41 displays the steps required to properly setup the fluidics system after a cassette has been inserted. If a cassette has not been inserted, this screen will direct the user to insert the cassette. Once inserted, the type of cassette is displayed at the top of the panel along with the compatible infusion tubing (i.e., stopcock type: automatic or manual) for that cassette. Note: If an anterior or posterior only cassette is inserted, the user can only select the associated mode.

1. Select Infusion/Irrigation Source - A selection from the Power IV Pole, Gravity or Pressurized options is made here by pressing the bottle associated with the source to be used. The desired source is highlighted in yellow when selected.
2. Select Infusion Cannula - Allows the user to select one of the following infusion cannula: 20, 23, 25 or 27+™ gauge.
3. (Optional) Specify Initial Fluid Level - Allows the user to set the starting level of the fluid in the container using the increment and decrement arrow buttons. This enables the system to accurately track the fluid level (in terms of percentage) as the operation progresses and alert the operator when fluid level is low.

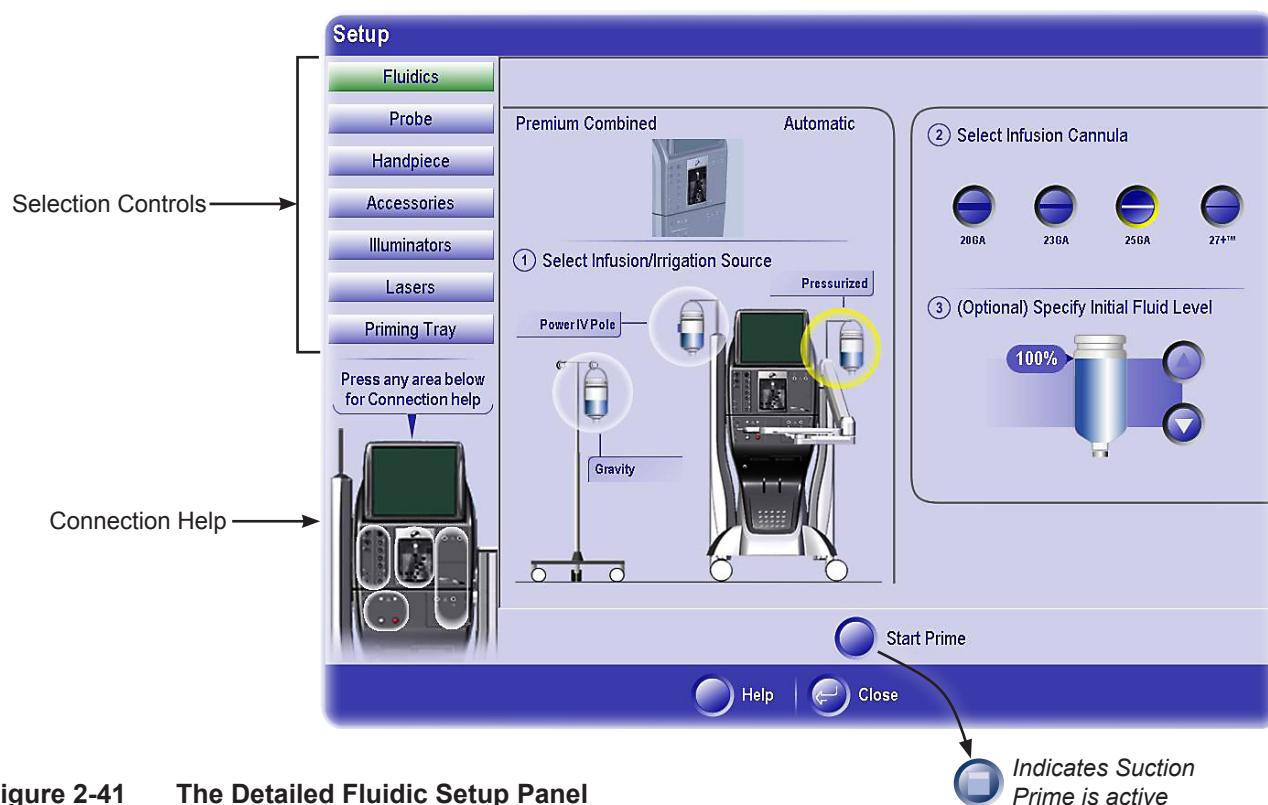


Figure 2-41 The Detailed Fluidic Setup Panel

Detailed Setup: Probe

The Probe Setup panel shown in Figure 2-42 displays the available probe selections and provides visual cues to guide the operator in connecting the selected probe to the system.

When the system detects that the operator has plugged in an *UltraVit®* probe, the probe type and gauge display are automatically updated and the “connected” icon appears next to the probe graphic. The system also “locks” the selection so another probe type cannot be selected. For low speed Vit probes, the “connected” icon does not appear and the selection button is not locked.

The Connection Guide shows the proper connections to the handpiece panel and the cassette for the selected probe.

Skip Probe Prime/Test - Indicates whether the operator wants to skip priming the selected vitreous probe. When the checkbox is checked, the system will not prime or test the vitreous probe when the user requests Prime & Test.

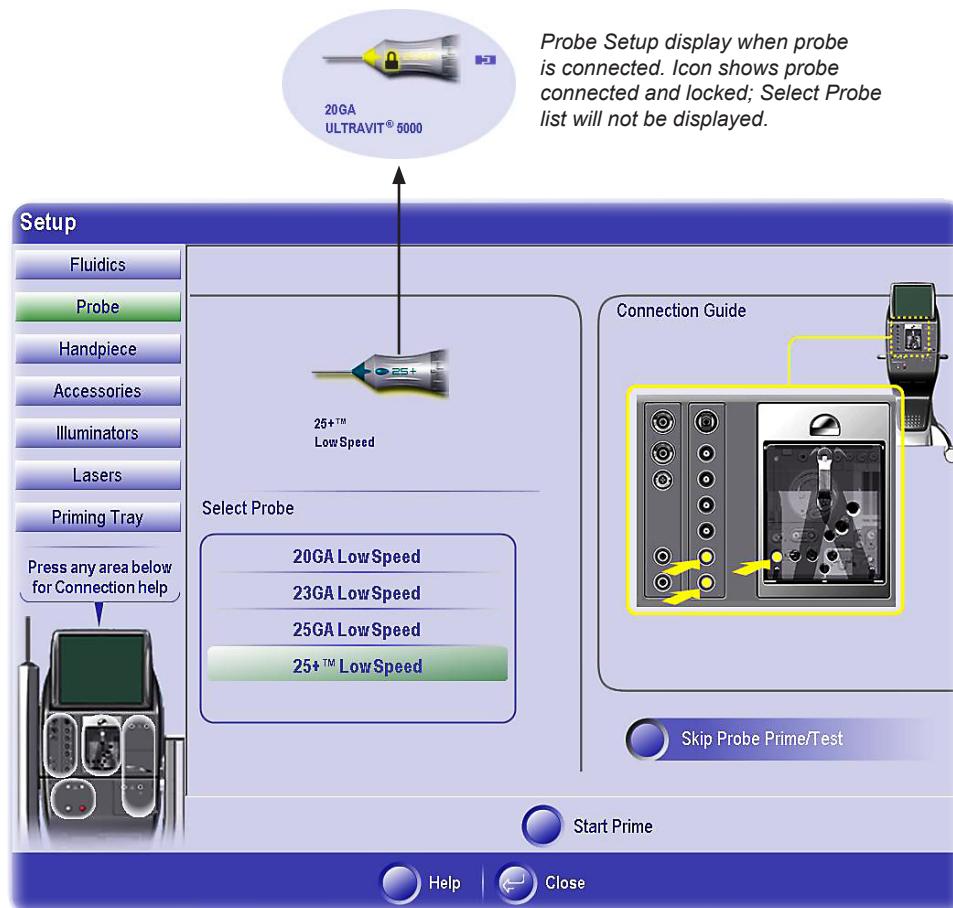


Figure 2-42 The Detailed Probe Setup Panel

Detailed Setup: Handpiece

The Handpiece Setup panel shown in Figure 2-43 displays the steps required to properly connect the various handpieces to the system.

1. Select Handpiece - Provides a selection of handpieces. When the system detects that the operator has plugged in the fragmentation, phaco, or *OZil®* handpiece, the handpiece type is automatically selected and the “connected” icon appears next to the selection list.
2. Select Tip - When a handpiece is selected, the Select Tip button appears and pressing the button opens a popup that will show a variety of tips that can be selected. Once selected, the tip will appear under the selected handpiece.
3. Connection Guide - This section shows an illustration of the connector panel and highlights the connections for the selected handpiece.

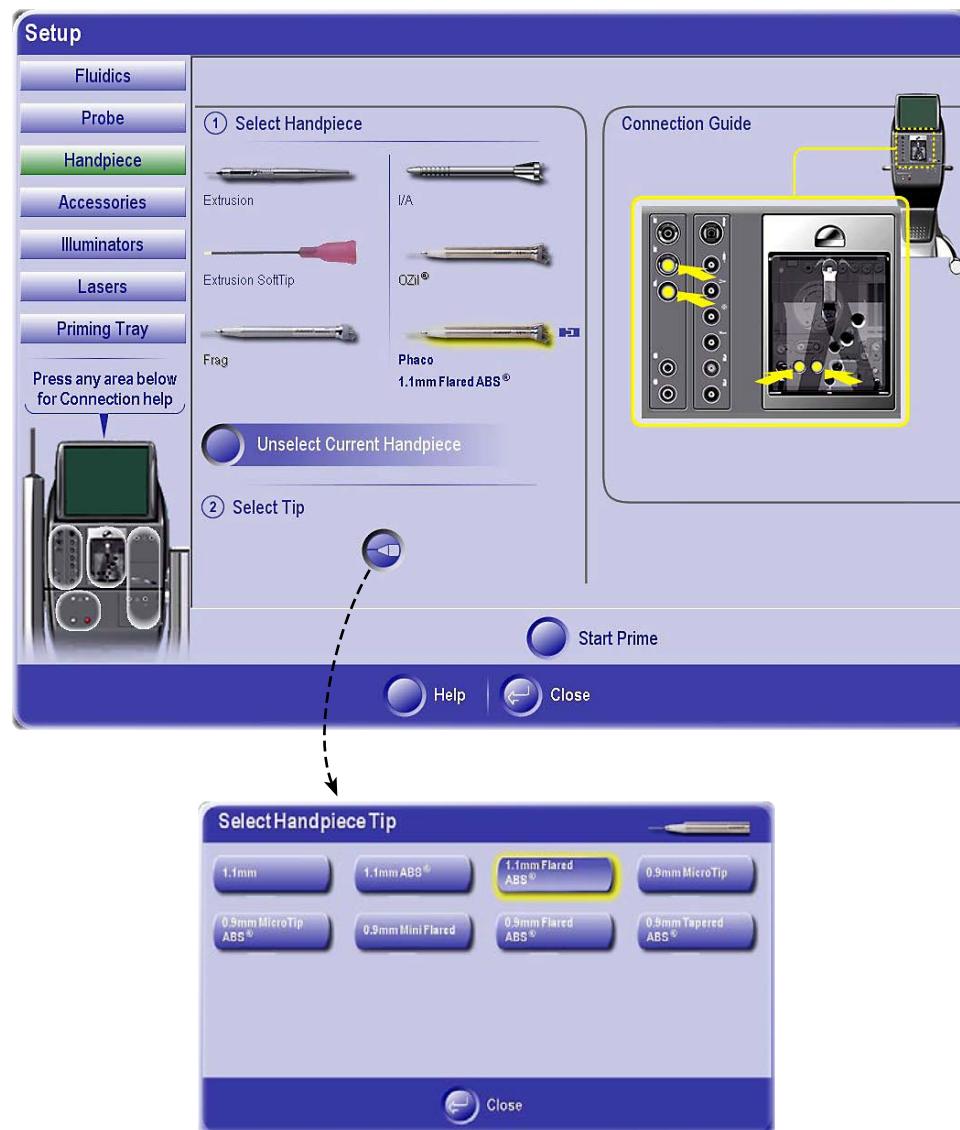


Figure 2-43 The Detailed Handpiece Setup Panel

Detailed Setup: Accessories

The Accessories setup panel shown in Figure 2-44 displays the steps required to properly connect the following accessories:

- Scissors
- Viscous Fluid Controller
- Forceps
- Auto Gas Fill
- Diathermy

1. Select Optional Accessory - Provides a selection of accessories. When the system detects that the operator has connected the accessory, that accessory type is automatically selected and the “connected” icon appears next to it in the selection list.

Confirm Connection - This button is present when the user has selected an accessory that is not currently detected as connected by the system. When this button is pressed, the system assumes that the currently selected accessory has been connected (even though it was unable to detect it). However, since the system did not auto-detect the connection, it will not lock the user from selecting the type of the accessory (e.g., type of scissors).

2. Connection Guide - This section shows an illustration of the connector panel, and highlights the connections for the selected accessory.



Figure 2-44 The Detailed Accessory Setup Panel

Detailed Setup: Illuminators

The Illuminators setup panel shown in Figure 2-45 allows the operator to view and select illuminator port and connection options.

1. Select Illuminator Port - Displays the endoilluminator probe the operator has chosen and/or inserted in the indicated illuminator port. When the system detects that a probe is plugged into a port, the Illuminator Type is automatically displayed and the “connected” icon appears next to the selection control. The system also “locks” the user from selecting another illuminator type.
2. Select Illuminator Type - When a port is selected in the Select Illuminator Port section (1), this section displays a scrolling list of Illuminator Types that can be assigned to the selected port. This section is not visible if the system has detected that a probe is connected to the selected port (connected and locked icons displayed).

The Connection Guide shows the proper connections to the illuminator panel for the selected probe.



Figure 2-45 The Detailed Illuminator Setup Panel

Detailed Setup Screen: Lasers

The Lasers Setup panel shown in Figure 2-46 allows the operator to view and select laser port and connection options for the various laser delivery devices.

1. Select Laser Port - Displays the laser delivery device the operator has chosen and/or connected to the indicated laser port. When the system detects that a device is connected to the port, the “connected” icon appears and the system “locks” the selection.
2. Select Laser Type - Shows the Laser type the operator has chosen and/or inserted for the highlighted laser port. The following laser types are selectable:
 - Endo
 - Laser Indirect Ophthalmoscope (LIO)

The Connection Guide shows the operator where to connect the device to the laser panel.



Figure 2-46 The Detailed Laser Setup Panel

Detailed Setup Screen: Priming Tray

The Priming Tray Setup panel shown in Figure 2-47 displays the suggested instructions for use of the priming tray according to the current connections and system configuration (i.e., push prime or suction prime).

NOTE: Push prime occurs when a cassette is inserted into the system at the beginning of a surgical case. During push prime, irrigation solution is "pushed" through both the irrigation and aspiration lines. Suction prime is used in the event an accessory must be re-primed after the surgical case has started. In this situation, the handpiece must be inserted into a container of sterile solution, and priming is accomplished through suction (aspiration) pulling the solution from the container.



Push Prime Setup Screen



Figure 2-47 The Priming Tray Set Up Screen

Detailed Setup: Help

When Video Help is selected, the popup shown in Figure 2-48 is displayed offering a list of help topics. Once the topic is selected, the user can choose between Video Help and Wizard Help. Pressing the Video Help button launches a help video that plays completely through the video for the selected topic. Wizard Help plays the same video but adds textual information and stops at various points to give the user a chance to perform the required actions before continuing.

The controls on the Video Help Display operate as follows:

- Start - Places the video at its beginning.
- Rewind - Rewinds the video one segment.
- Play/Pause - This button is labeled Pause when the video is playing and Play when the video is not playing.
- Forward - Forwards the video to the next segment.
- End - Forces the video to be forwarded to the end.
- Move Left - Moves the entire video popup to the left side of the surgical panels.
- Move Right - Moves the entire popup to the right side of the surgical panels.
- Close - Closes the Video Help popup.

The controls on the Wizard Help Display operate as follows:

- Previous - Rewinds the video one segment and pauses.
- Replay - Rewinds the video one segment and play continues.
- Continue - Resumes video play.
- Next - Advances the Help screen to the next video segment and associated help text.
- Move Left - Moves the entire video popup to the left side of the surgical panels.
- Move Right - Moves the entire popup to the right side of the surgical panels.
- Close - Closes the Video Help popup.

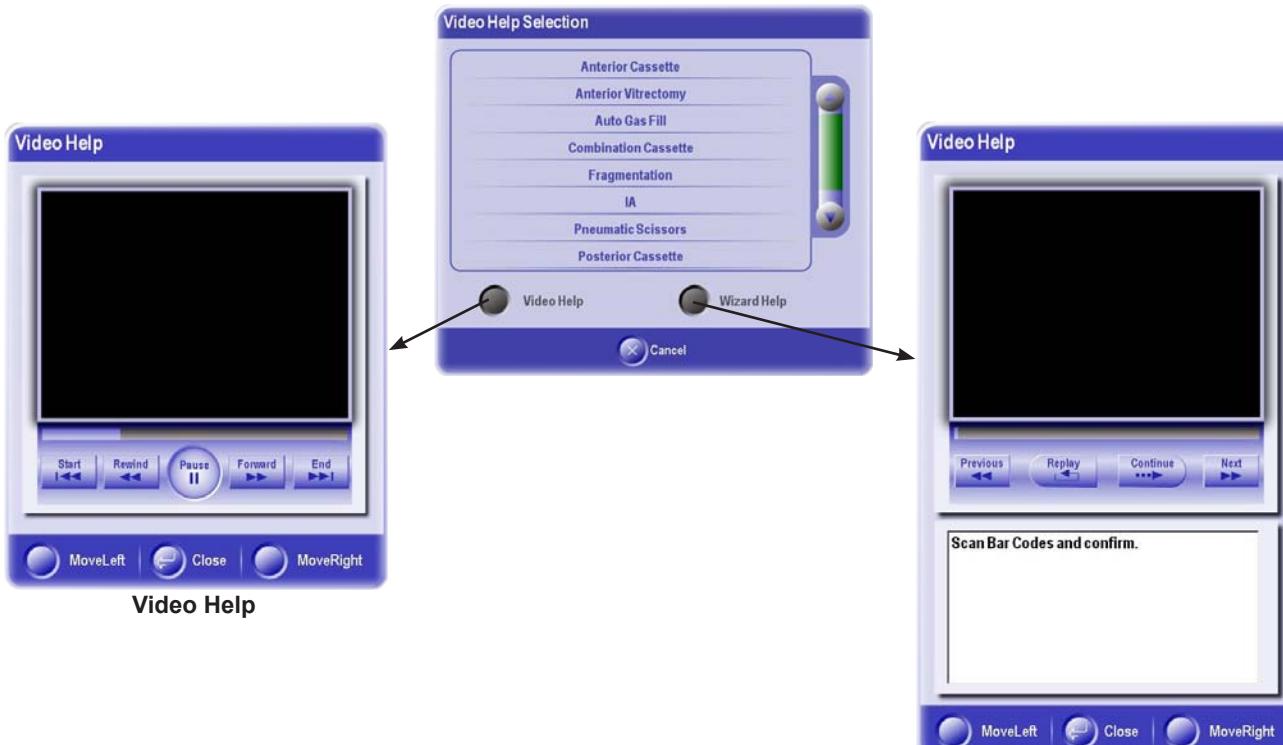


Figure 2-48 Video Help Popups

Wizard Help

Start Prime Button And Popup

After the instrument connections are complete, pressing the Start Prime button displays the Prime & Test Status popup (see Figure 2-49) and begins the prime/test process for the current setup (Figure 2-49 shows possible variations as determined by the current setup and user actions). The status bar uses different colors to indicate the progress and completion status of each segment of the prime/test process.

- *Partial green bar* - indicates that the current segment is in progress.
- *Complete green bar* - indicates that the process related to that segment has finished with no errors.
- *Yellow bar* - indicates that the user has cancelled the process by pressing the Stop button at the end of the bar.
- *Red bar* - indicates that the process related to that segment has failed with errors.

When the Prime and Test is complete, the system will transition to the Surgery screen.

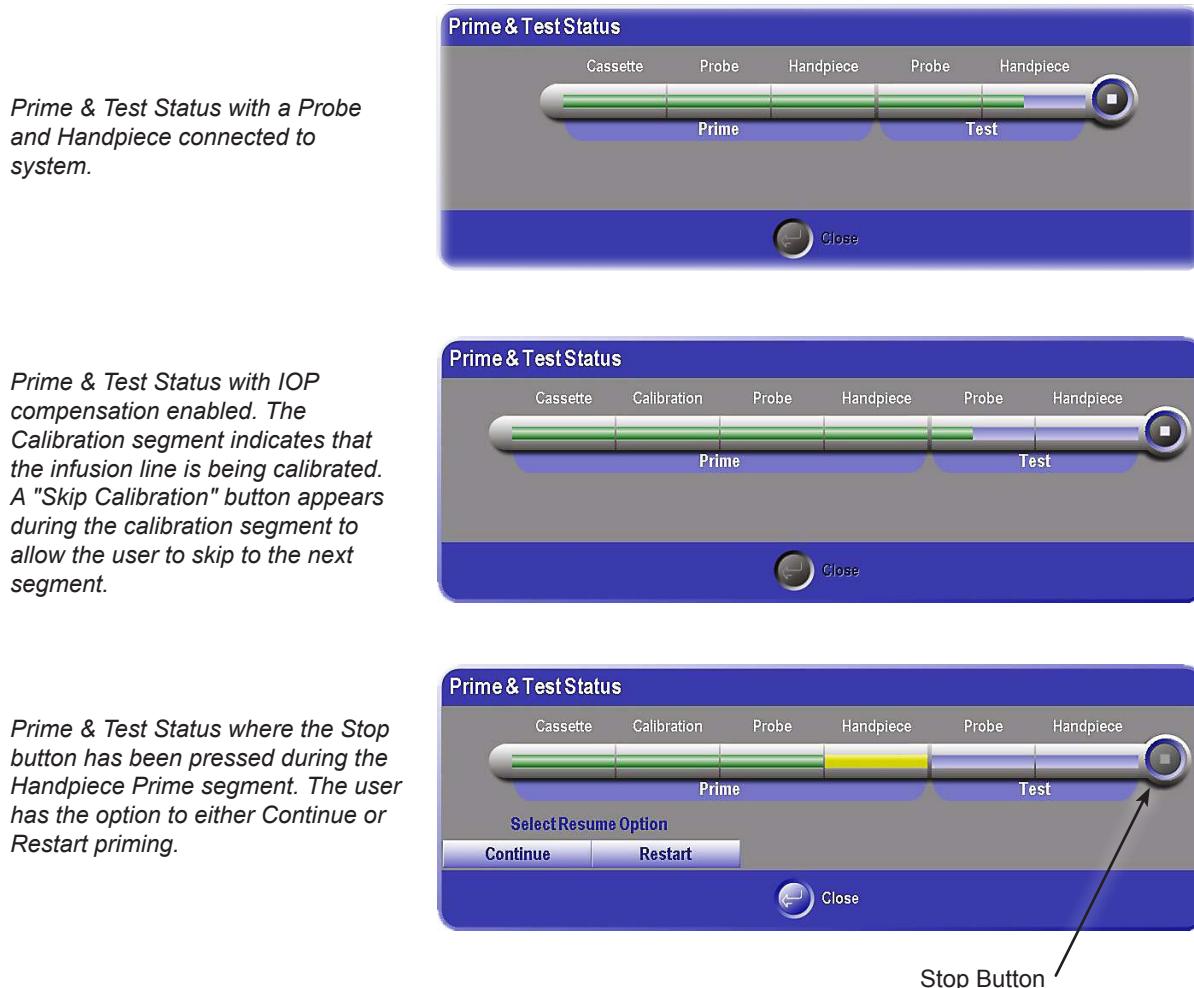


Figure 2-49 Prime & Test Status Bar Variations

Consumables Button And Popup

Pressing the Consumables button displays the Consumables popup shown in Figure 2-50. In the Consumables popup the user can view, add, or remove the consumables used for the current surgical case. The top of the popup displays the items that have been added to the current case either through this popup or the bar code scanner.

The bottom of the popup shows the list of consumables that can be added to the case. Scrolling through the consumables list is accomplished using the scroll bar and arrows next to the list.

The operator can choose to view all consumables or filter the list to show only Packs, Accessories, or IOL's by pressing the associated button on the filter list.

To add an item: Select the item from the consumables list in the bottom of the popup then press the Add button. The selection will be added to the top list as an item used for the current case.

To remove an item: Select the item from the list in the top of the popup then press the Remove button. The selection will be removed from the top list.

NOTE: Refer to the Directions For Use (DFU) included with each accessory kit/consumable pack for detailed instructions on how to setup that accessory.



Figure 2-50 Consumables Popup

SURGERY SCREEN

The Surgery Screen shown in Figure 2-51 is organized in the following way:

- *Menu Bar* - This menu bar is context aware and changes the options depending on the surgical mode. Status indicators for the various functions will appear with either a green check mark indicating the function is ready for use (i.e., Primed), or a red X indicating the function requires user action to prepare for use (i.e., Not Primed).
- *Surgery Panels* - Each Surgery Panel corresponds to a “Surgical Function” and contains the various controls necessary to control each function.
- *Step Panel* - The Step Panel allows the user to select Surgical Modes and Submodes by pressing a Step Button and a Submode Button. The look of the Step Panel depends on which Surgical Procedure (discussed later) is selected.
- *Save Button* - The Save button opens the Quick Save popup.
- *Modify* - The Modify button opens the Modify Procedure popup.

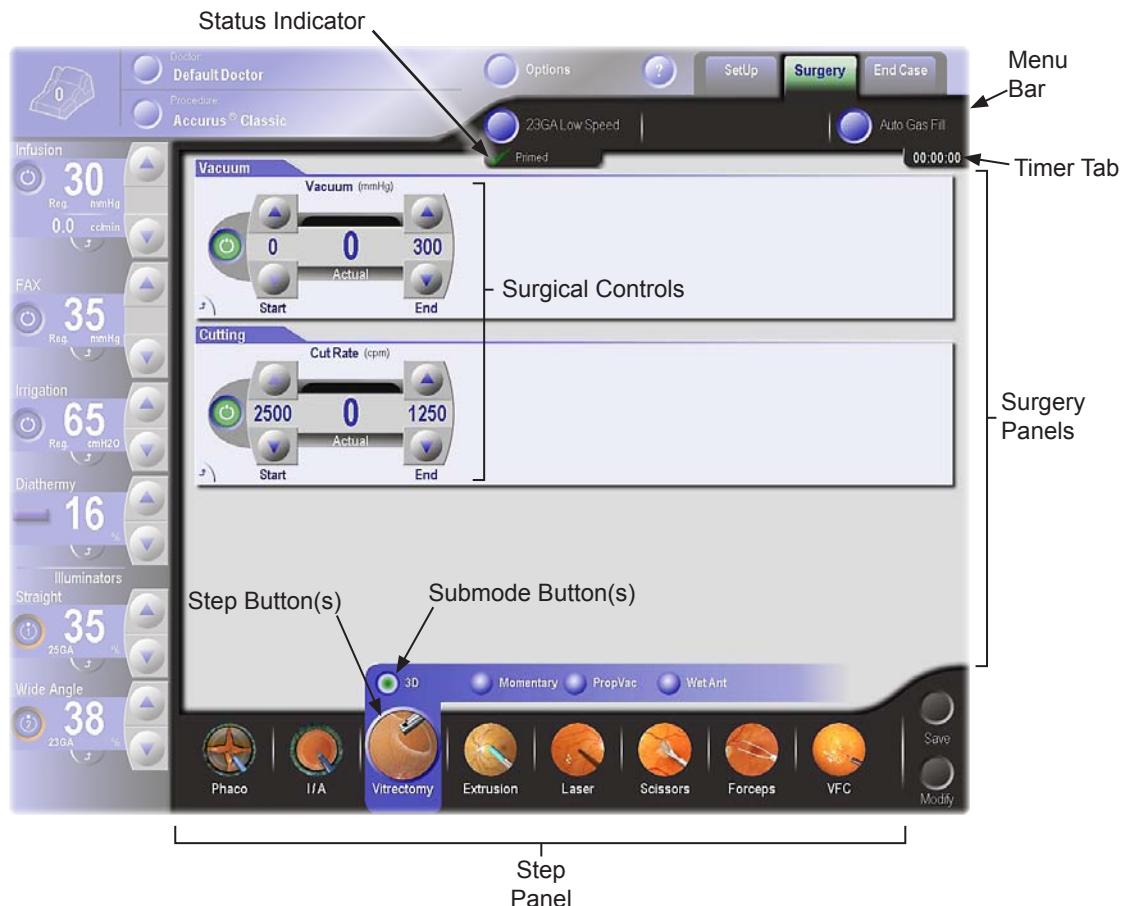


Figure 2-51 The Surgery Panel

The General Purpose Timer

The Timer provides a visual display for counting up and counting down from a pre-configured value. Pressing the Timer Tab (00:00:00) displays the Timer Configuration popup shown in Figure 2-52. The timer features the following functionality:

- Pressing the Timer Tab when it is running will stop the timer.
- Pressing the Timer Tab when it is not running will launch the Timer Configuration popup.
- Pressing the Start button from the Timer Configuration popup starts the timer and closes the popup.
- If the timer is started when the readout is 00:00:00, it will count up indefinitely.
- For countdown mode, enter a starting time using the keypad then press Start. The timer generates an audible tone when it reaches 00:00:00.
- At the end of each case, the counter stops counting and is reset to 00:00:00.



Figure 2-52 Timer Configuration Popup

Surgery Screen: Surgical Controls

The surgical panels make use of the surgical controls to change the values of the associated surgical functions. The controls provide a variety of information and capability to the user. As an example, the Vacuum control is shown in Figure 2-53.

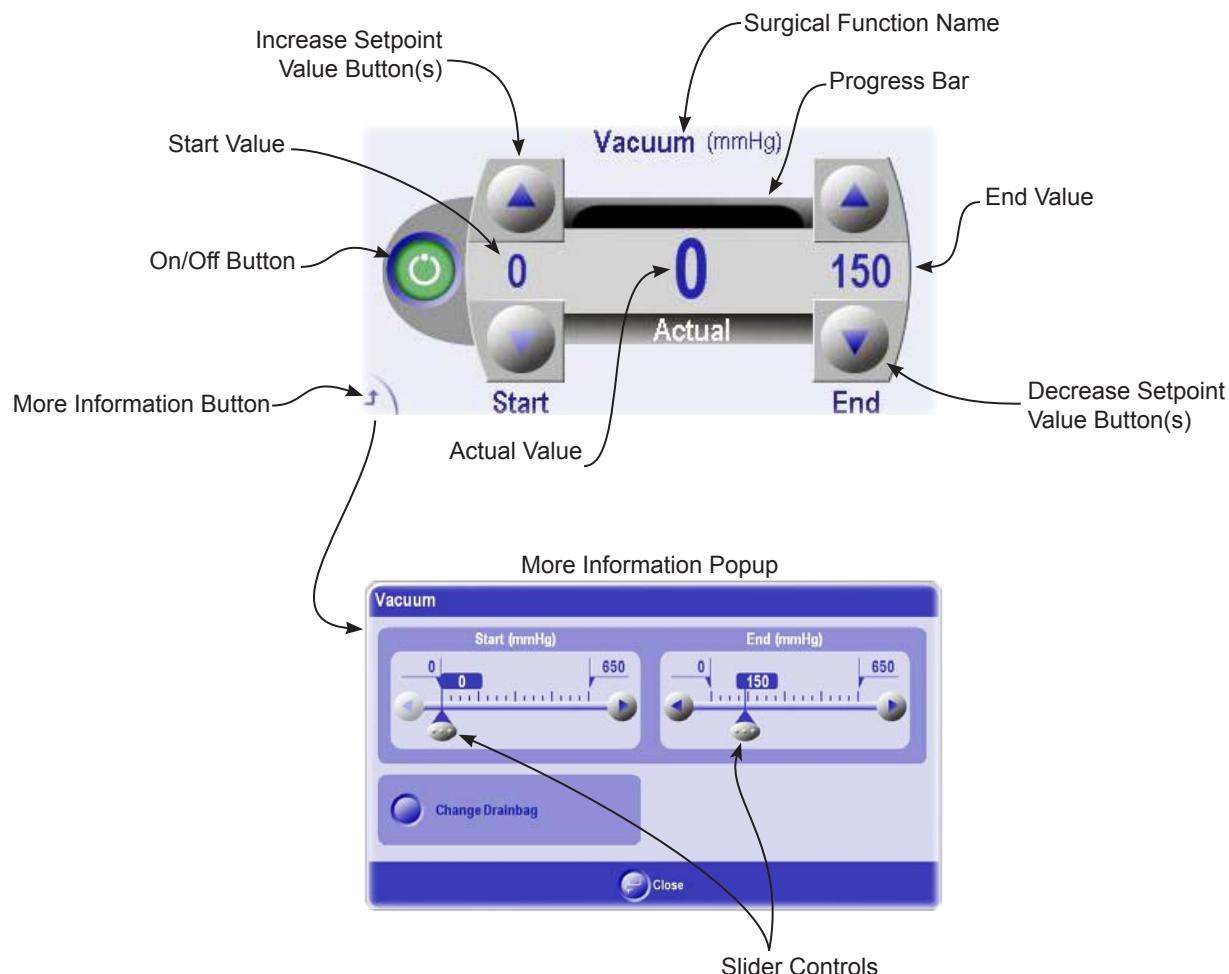


Figure 2-53 Vacuum Control and More Information Popup

The surgical controls contain some or all of the functionality described here:

- **On/Off Button** – Toggles the function on and off. A green button indicates that the function is on while a dark gray button indicates that the function is off.
- **Up/Down Arrow Buttons** – Increase/decreases the associated setpoint value. The button face indicates whether or not the associated setpoint can be increased or decreased. The button is disabled when increases/decreases are not allowed.
- **Start Value** – Shows the current setpoint at the treadle starting position.
- **End Value** - Shows the setpoint at full treadle.

- *Actual value* – Displays the current value of this parameter and depends on the position of the footswitch treadle. The actual value is shown as an absolute value and also as a relative percentage of the maximum via the progress bar.
- *Surgical function name* – The value displayed represents the surgical function being manipulated by the On/Off or Action buttons.
- *More Information Button* - Pressing the More Information button displays the More Information popup where the setpoint values can be changed in greater detail.
- *Slider Controls* - On the More Information Popup, the slider controls adjust a value by pressing and dragging the slider to the desired value location.

Surgery Screen: Surgical Controls - More Information Popup

When the More Information button is pressed on a surgical control, a More Information Popup is displayed as shown in Figure 2-53 (Vacuum Setting shown in this example). Settings modified here take effect immediately (i.e., before the user exits the popup). Also, each control will have a slightly different popup given that some controls have more functionality than others.

Surgery Screen: Surgical Controls - Surgical Control Options

For some surgical configurations, such as calibrating scissors, it is necessary to provide additional options as shown in Figure 2-54.

- *On/Off button* - Toggles the option On and Off. This control is disabled when the functionality is not available.
- *Left Option button* - Allows the user to initiate the function assigned to this button ("Start" in Figure 2-54).
- *Right Option button* - Allows the user to initiate the function assigned to this button ("Close" in Figure 2-54).
- *Save Calibration Values* - Pushing this button saves calibration values.



Figure 2-54
Surgical Control Option

Surgery Screen: Surgical Controls - Surgical Control Drop Lists

For some controls in certain configurations it is necessary for the user to define additional parameters. Such parameters might include the Cutting Table, whether Linear or Fixed Flow is desired, or Dynamic Rise Time among others. When such a choice is needed, a drop list appears near the surgical control as shown in Figure 2-55.

NOTE: The control is shown in the "Advanced Display Mode" which is a selection made in the Doctor Settings display. Go to "Options/Settings/Doctor/General" and the display modes are shown on the right of the display. For additional information see Menu Bar: Options in this section of the manual.

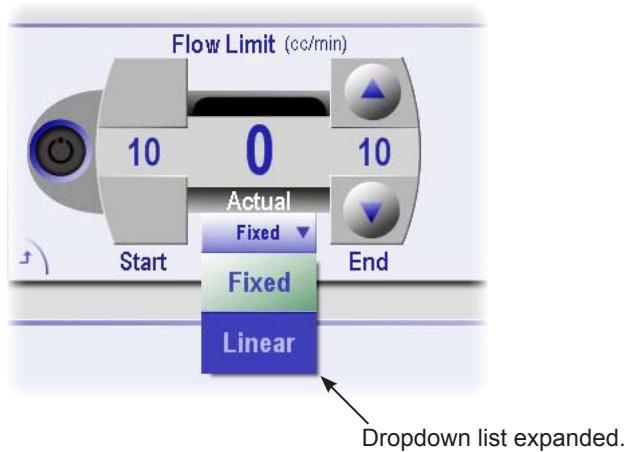


Figure 2-55 Surgical Control with Dropdown List (Advanced Display Mode)

Surgery Screen: Surgical Steps

A "Surgical Step" identifies a related set of activities performed during a surgical case. Examples are "Membrane Peeling" and "Core Vitrectomy." A Surgical Step is associated with a Surgery Mode and contains unique information relevant to that mode such as the sub mode, which functions are on, and various values of surgical parameters. Selecting a Surgical Step determines which surgical functions are available. Surgical Steps that are grouped together form a Surgical Procedure.

Surgery Screen: Surgical Procedures

A Surgical Procedure describes which "Surgical Steps" are most likely to be performed during a surgery. The goal is to organize the screen in such a way that the surgeon can select steps "from left to right" as the surgery progresses. The user can create custom procedures or modify existing procedures. A procedure must contain at least one step and can contain as many steps as desired.

Note: See "Menu Bar: Procedure Selection" found earlier in this section for detail information on creating and editing procedures.

Surgery Screen: Surgical Procedures - Accurus® Classic Procedure

The Accurus® Classic procedure is a special procedure that is designed to look similar to the Accurus® instrument with the exception that it contains the laser step. The Accurus® Classic procedure has several unique properties:

- Steps cannot be added or removed.
- Steps cannot be moved.
- Steps cannot be renamed.
- All Steps will always fit on the screen so there's no need for scrolling.
- The sub mode buttons will always be visible if there is more than one sub mode for that step.

The Accurus® Classic procedure contains one step for each surgery mode. However, at any point in time only a subset or a “View” of the steps is displayed. The Views differ depending on:

- The Fluidics Operating Mode (Combined, Anterior, or Posterior)
- The connected U/S handpiece (defaults to Phaco if no U/S handpiece is connected)

The screen shown in Figure 2-56 shows the Accurus® Classic procedure in combined mode.



Figure 2-56 Accurus® Classic Surgery Screen

Surgery Screen: Surgical Procedures - Custom Procedure

Custom Procedures can contain any combination of steps in any order and with user defined names as shown in Figure 2-57.

Custom Procedures are intended to contain all the steps that the user has included to perform a certain task. However, in some cases the user may need to do something that is not included in the current procedure. In addition to the manual method of adding surgical steps through the Modify Procedure screen as described previously in this section, the system automatically adds relevant step(s) when an instrument (such as a vitreous probe) is connected. For example if the user suddenly requires the use of the laser, the system automatically adds a laser step to the end of the procedure when it detects the connection of a laser probe. Also, if a laser probe is already connected when the procedure is selected, a laser step is added to the end of the procedure.

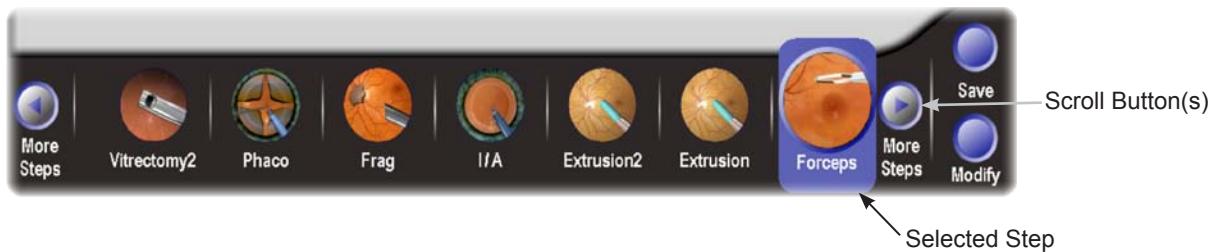


Figure 2-57 **Surgical Step Panel - Custom Procedure**

Surgery Screen: The Surgical Step Panel

The Surgical Step panel organizes the set of activities (steps) to be performed during a surgical procedure in a left to right sequence. The procedure may be customized to meet the needs of the surgeon and the case to be performed. The Step panel provides the following functionality:

- Shows which step is currently selected (note that a step is associated with only one surgical mode).
- Shows which sub mode is currently selected for that step.
- Allows the user to select a new step.
- Allows the user to select a new sub mode.
- Allows the user to select a “hidden” step (if applicable).

A selected step has the following properties:

- The area behind the icon is highlighted in blue.
- The icon is animated.
- Buttons for submodes are shown above the step button.

The Step buttons act as radio buttons in that only one step at a time can be selected and a step must always be selected at any point in time.

The Scroll buttons allow the user to navigate to “hidden steps,” i.e., steps that are either to the left or the right of the visible steps. The scroll buttons are only visible if the current procedure contains more steps than can fit on the Step panel.

Figure 2-58 shows an example of a Step panel with three hidden steps to the right. The Right Scroll button is enabled and pressing it displays a list of the hidden steps. Any of the steps can be selected from the list. The selected step will be highlighted as the selected step on the panel and placed in the right most position.

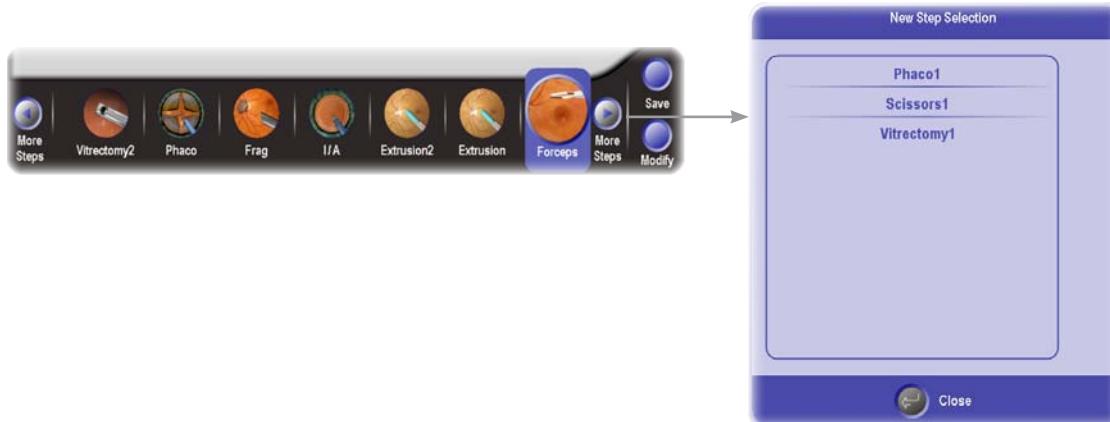


Figure 2-58 Surgical Step Panel Scroll Buttons

Surgery Screen: Surgical Submode Buttons

For *Accurus®* Classic procedures, the submode buttons are always displayed as shown in the Figure 2-56. The submode buttons act like radio buttons (just like the step buttons) and the currently selected sub mode is highlighted.

For Custom procedures, submode display behavior is determined by the Doctor Settings. If "Display Submodes in Custom Procedures" is disabled, the submode buttons are only displayed when the user presses the currently selected step. The submode buttons are then displayed for five seconds enabling the user to select the desired submode. After five seconds, the submode buttons will disappear.

If "Display Submodes in Custom Procedures" is enabled, the submode buttons are always displayed. **Note: VFC submode buttons are always displayed regardless of the Doctor Settings.**

SURGICAL MODES AND SUBMODES

The *Constellation®* Vision System offers nine surgical modes that can be customized to meet the needs of each surgeon. Table 2-2 lists each mode and its associated submodes.

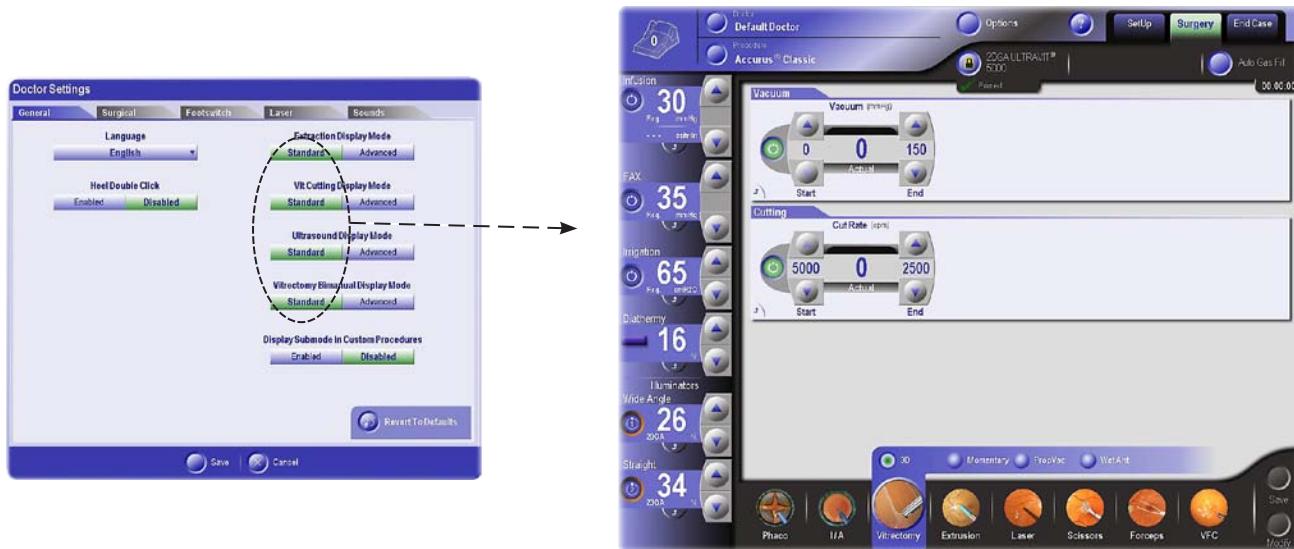
TABLE 2-2. SURGICAL MODES AND SUBMODES

| MODE | SUBMODES | | | | | BIMANUAL (Advanced Mode) |
|--|---------------------------|-------------------------------|---|----------------------------|--------------------------|---|
| Vitrectomy (Vit) | 3D (Post, Comb)* | Momentary (Post, Comb)* | Proportional Vacuum (Post, Comb)* | WetAnt (Ant, Comb)* | VitDry (Ant)* | Forceps (Post, Comb)* |
| Phaco | 3D (Ant, Comb)* | Burst (Ant, Comb)* | Pulsed (Ant, Comb)* | Continuous (Ant, Comb)* | Custom** (Ant, Comb)* | |
| Fragmentation (Frag) | 3D (Post, Comb)* | Fixed (Post, Comb)* | Linear (Post, Comb)* | Momentary (Post, Comb)* | | |
| Irrigation/Aspiration (I/A) (Ant, Comb)* | | | | | | |
| Extrusion (Post, Comb)* | | | | | | |
| Laser (Post, Comb)* | | | | | | |
| Scissors | Multicut (Post, Comb)* | Proportional (Post, Comb)* | | | | Forceps (Post, Comb)* |
| Forceps (Post, Comb)* | | | | | | |
| Viscous Fluid Control (VFC) | Extract (Post, Comb)* | Inject (Post, Comb)* | | | | Vacuum (Inject only) (Post, Comb)* |
| <small>* Indicates the type of cassette that must be installed to enable the specified mode. Ant = Anterior Cassette; Post = Posterior Cassette; Comb = Combined Cassette.</small> | | | | | | |
| <small>** Available in the Advanced View only.</small> | | | | | | |

Each surgical mode has a set of associated surgical panels. The following settings affect how some panels are displayed:

- **Standard vs. Advanced display mode** - The standard display mode offers a minimum number of options in the associated panel. In advanced display mode, the displayed panels offer optional controls for setting and configuring functions. The default mode is Standard. Advanced display mode is available in the following panels: Extraction, Vit Cutting, Ultrasound, and Vitrectomy Bimanual. Selecting Standard or Advanced mode is done in the Options\ Doctor Settings\ General screen (see Figure 2-59).
- **Vacuum mode vs. Flow mode** - By default, the posterior modes show the vacuum panel for vacuum mode, and the anterior modes show the aspiration panel for flow mode (if available). In Advanced display mode, the Function mode panel allows the user to select between Flow and Vacuum modes. Changing modes will change the panel accordingly.
- **Bimanual mode** - Vit, scissors, and VFC modes offer the surgeon the option of controlling two instruments simultaneously such as a vitreous probe and a pair of forceps (in Vit mode). This is referred to as Bimanual mode and the additional instrument is activated by pressing the Bimanual button.

STANDARD DISPLAY MODE



ADVANCED DISPLAY MODE

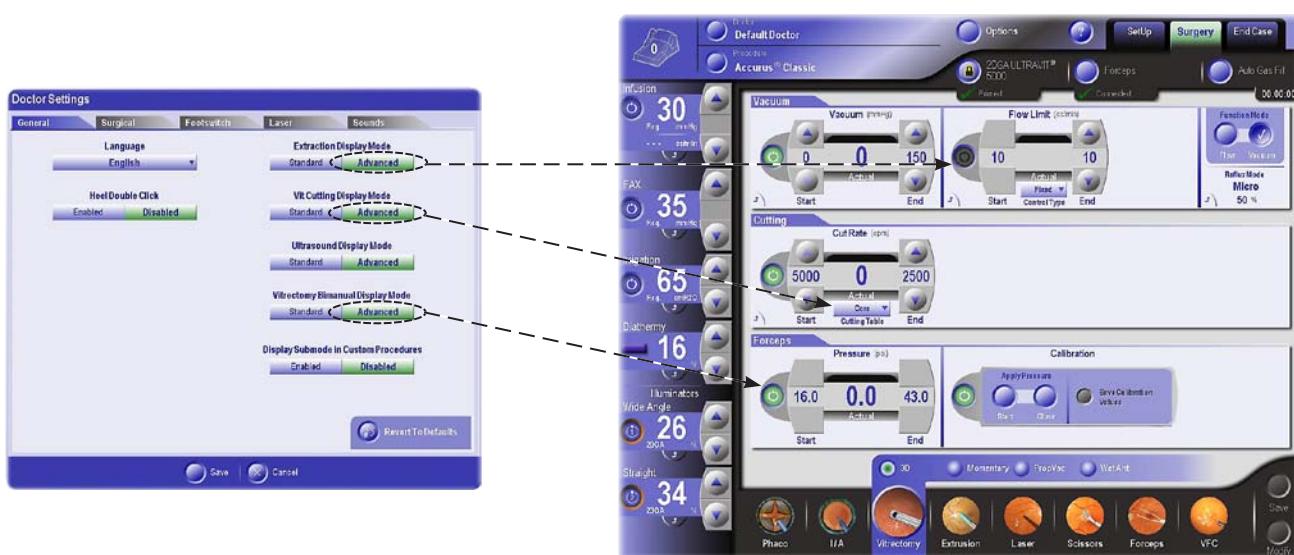


Figure 2-59 Standard versus Advanced Display Modes: The Standard mode provides the basic controls necessary in each surgical step; the Advanced mode offers additional controls that enable the user to utilize all the capabilities of the Constellation® Vision System.

VITRECTOMY MODE

Vitrectomy mode provides vitreous cutting and vacuum using a pneumatically powered vitrectomy probe connected by tubing to a pulsed air pressure source and a vacuum port. Five submodes are available, each with its own default cut rate and vacuum level. Values are adjusted using touch arrow keys, even when the footpedal is depressed. Cutting and/or vacuum begins when the footpedal is pressed.

Vitrectomy: 3D SUBMODE

In the 3D submode shown in Figure 2-60, the user controls both the vitreous cut rate and the vacuum pressure linearly. This submode allows for setting the treadle start and end values for both the cut rate and the vacuum pressure.

In 3D submode, vacuum delivered to the probe and the probe cutting rate are both regulated by the amount of footpedal depression. The display contains adjustable values for vacuum level at footpedal start and at full depression; and cut rate at footpedal start and at full depression. The unique features of this mode are:

- Vacuum can be set to start at 0 and rise to its maximum setting at full footpedal depression, while the cutting rate can be set to start at its maximum setting and decrease as the footpedal is depressed (or any combination thereof).
- To prevent generating excessive flow when the footpedal is first depressed, the vacuum level is ramped up from 0 to the set starting level during the first part of the pedal travel.
- When the Start Limit is greater than 0, the vacuum uses the Ramping % selected in the Doctor's Settings to ramp from 0 to the Start Limit.

The controls for each panel in 3D submode have the following functions:

Vacuum Panel:

- On/Off - Turns vacuum on or off.
- Vacuum Start Up/Down Buttons - Set the vacuum level at treadle start.
- Vacuum End Up/Down Buttons - Set the vacuum level at full treadle.
- Vacuum More Information Button - Displays the More Information popup allowing the user to make changes using slider controls. Also provides panel specific configuration capabilities (such as drainbag change).

The following Vacuum panel controls are available only in the Advanced view:

- Flow Limit On/Off Button - Turns flow limit on or off. When the maximum rate is reached the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the Start and End values.
- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for the flow rate.
- Flow Limit More Information Button - Displays the Flow Limit More Information popup.
- Flow/Vacuum Toggle - Switches between Flow Mode and Vacuum Mode.
- Flow Limit Control Type Drop List - Determines whether the flow limit is fixed or linear. In Fixed, the limit is constant regardless of the flow level. In Linear, the limit varies depending on the flow level.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the More Information popup that allows for changing the current mode and the setpoint associated with it.

Cutting Panel:

- Cut Rate On/Off Button - Turns the cutter on or off.
- Cut Rate Start Up/Down Buttons - Set the cut rate at treadle start.
- Cut Rate End Up/Down Buttons - Set the cut rate at full treadle.
- Cutting More Information Button - Displays the More Information popup.
- Cutting Table Drop List (Advanced view only) - Allows selection of port open duty cycle that is appropriate for the procedure to be performed.

Core - Provides the maximum port open duty cycle control suited for core vitrectomy where higher flow rates and efficiency are desirable.

50/50 - Provides a 50% port open duty cycle control for those users who prefer that the cutter is open and closed for the same amount of time.

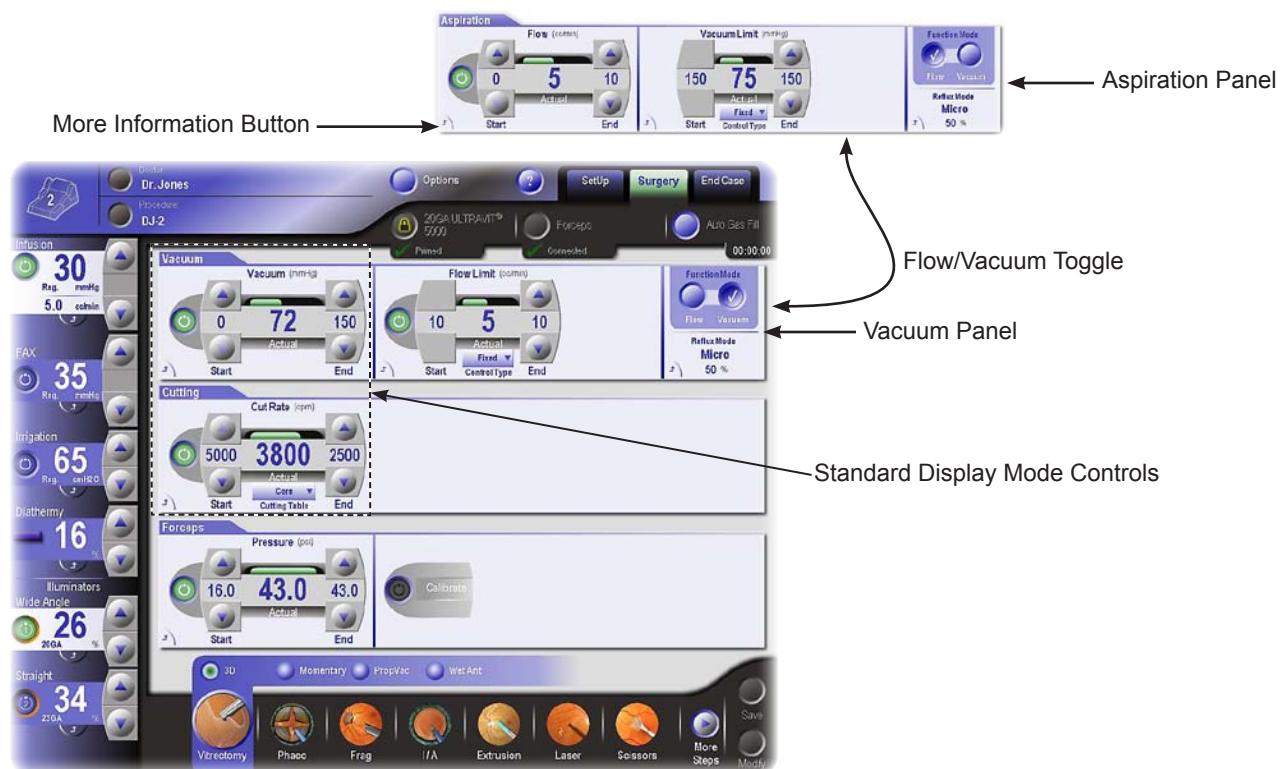
Shave - Provides the minimum port open duty cycle suited for removing delicate tissue (such as vitreous shaving and membrane dissection) where lower flow rates are desirable.

Aspiration Panel (Flow mode-Advanced view only):

- Flow On/Off Button - Turns flow mode on or off.
- Flow Start Up/Down Buttons - Set the flow level at treadle start.
- Flow End Up/Down Buttons - Set the flow level at full treadle.
- Flow More Information Button - Displays the More Information popup for a detailed view of the settings.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending on the vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup
- Flow/Vacuum Toggle - Switches between Flow Mode and Vacuum Mode.

Forceps Panel (Advanced view only):

- Pressure On/Off Button - Turns Bimanual mode on or off. When Bimanual mode is off the only option is to turn it on. When Bimanual mode is on, the forceps pressure can be set.
- Pressure Start Up/Down Buttons - Set the pressure at the start of treadle depression.
- Pressure End Up/Down Buttons - Set the pressure at full treadle.
- Forceps More Information Button - Displays the More Information popup.
- Calibration - When the calibration control is turned on, the control changes to one that allows a selection between Start and Close. When Start is selected the start pressure is applied to the port, and when Close is selected, the close pressure is applied to the port. If neither is selected then no pressure is applied to the port. Pressing the Save Calibration Values button saves the calibrated values.



Examples of Treadle Operation in Vit 3D Submode

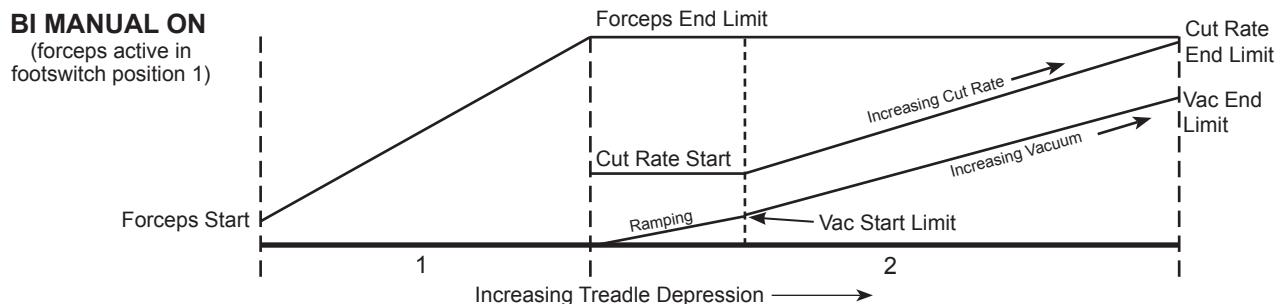
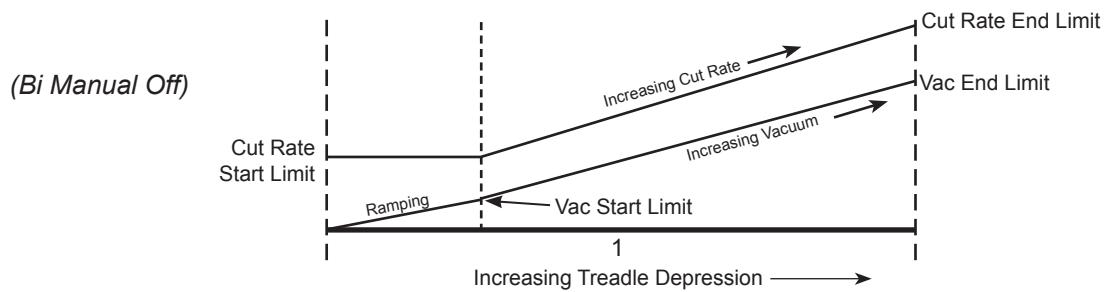
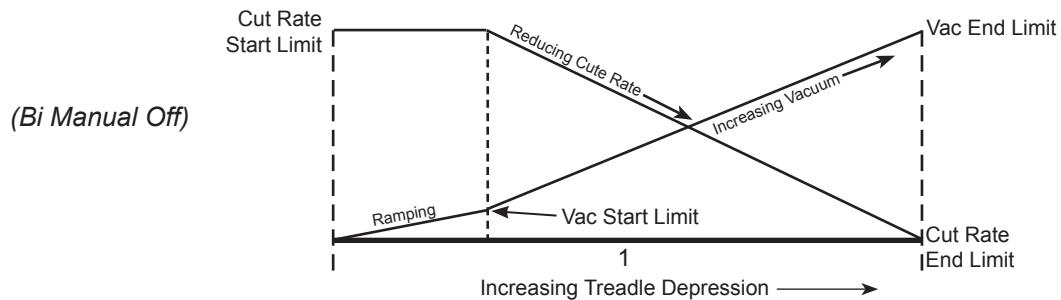


Figure 2-60 Surgery Screen: Vitrectomy Mode - 3D Submode (Advanced View shown)

Vitrectomy: MOMENTARY SUBMODE

The Momentary submode contains values for maximum vacuum limit and cut rate set point. As the footpedal is depressed the vacuum increases linearly up to the End limit with the actual vacuum displayed in the Actual Value box and its linear equivalent reflected in the progress bar. The End value can be adjusted using the Up/Down arrow buttons or selecting the More Information button to display the More Information popup that has a sidebar for large numeric adjustments in vacuum.

Probe cutting at a preset rate is activated when the applicable footswitch button is momentarily activated. The default activation button is the right horizontal button but it may be configured differently for each doctor. To view the current configuration, press the footswitch icon in the upper left corner of the display.

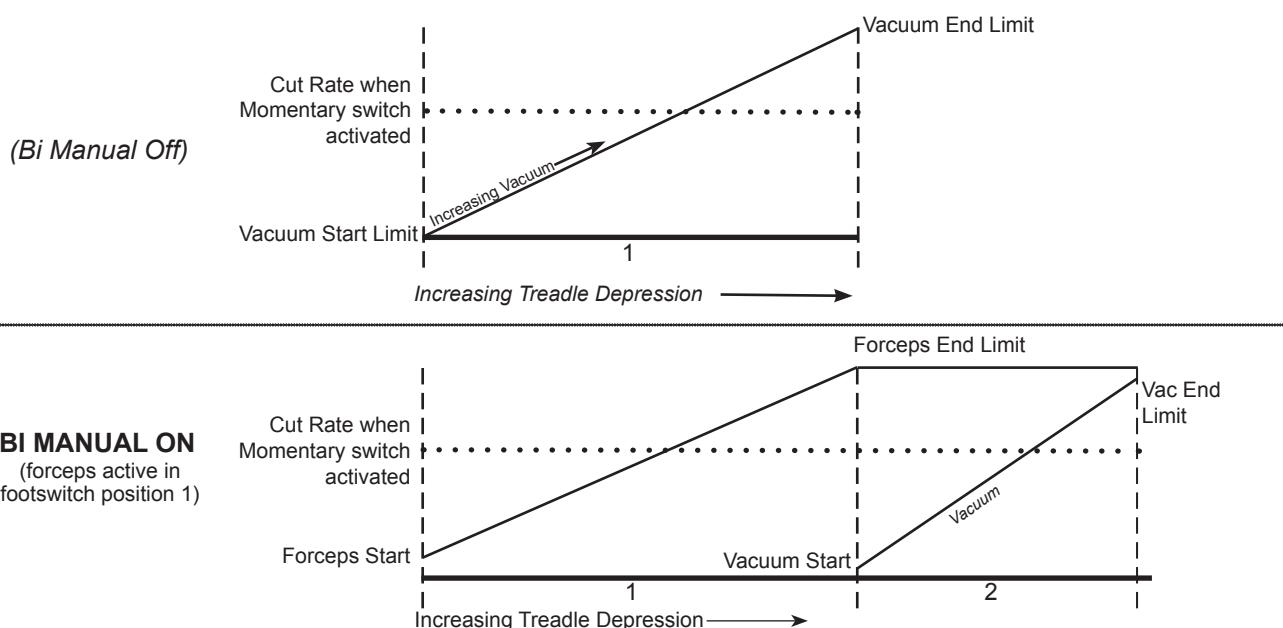
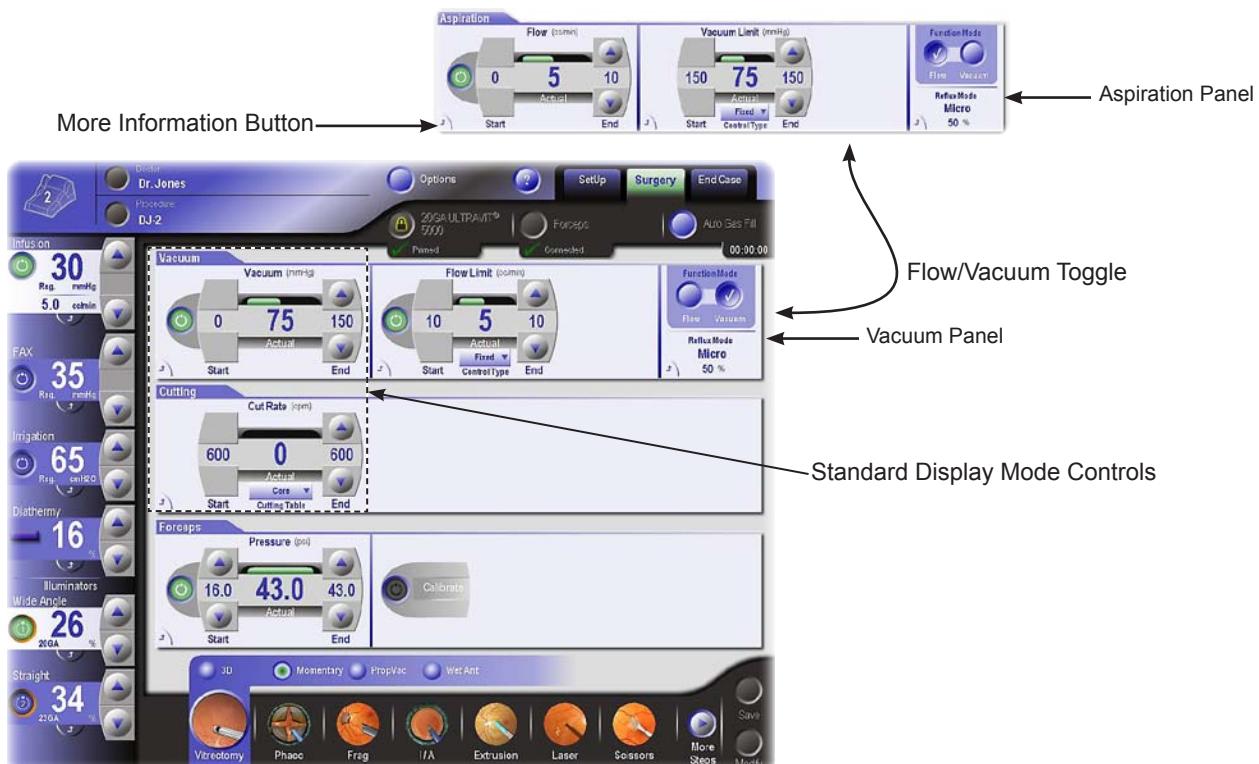


Figure 2-61 Surgery Screen: Vitrectomy Mode-Momentary Submode (Advanced View shown)

The controls for each panel in Momentary submode are the same as in 3D submode with the following exceptions:

- No Cut Rate Start Up/Down Buttons - Cut rate is a constant rate set by the End buttons and activated by the programmed button on the footswitch.
- No Vacuum (or Flow) Start Up/Down Buttons.

Vacuum Panel:

- On/Off - Turns vacuum on or off.
- Vacuum End Up/Down Buttons - Set the vacuum level at full treadle.
- Vacuum More Information Button - Displays the More Information popup, allowing the user to make changes using slider controls. Also provides panel specific configuration capabilities (such as drainbag change).

The following Vacuum panel controls are available only in the Advanced view:

- Flow Limit On/Off Button - Turns flow limit on or off. When the maximum rate is reached the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the End value.
- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for the flow rate.
- Flow Limit More Information Button - Displays the Flow Limit More Information popup.
- Flow/Vacuum Toggle - Switches between Flow Mode and Vacuum Mode.
- Flow Limit Control Type Drop List - Determines whether the flow limit is fixed or linear. In Fixed, the limit is constant regardless of the flow level. In Linear, the limit varies depending on the flow level.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the More Information popup that allows for changing the current mode and the setpoint associated with it.

Cutting Panel:

- Cut Rate End Up/Down Buttons - Set the cut rate at full treadle.
- Cutting More Information Button - Displays the More Information popup.
- Cutting Table Drop List (Advanced view only) - Allows selection of port open duty cycle that is appropriate for the procedure to be performed.

Core - Provides the maximum port open duty cycle control suited for core vitrectomy where higher flow rates and efficiency are desirable.

50/50 - Provides a 50% port open duty cycle control for those users who prefer that the cutter is open and closed for the same amount of time.

Shave - Provides the minimum port open duty cycle suited for removing delicate tissue (such as vitreous shaving and membrane dissection) where lower flow rates are desirable.

Aspiration Panel (Flow mode-Advanced view only):

- Flow On/Off Button - Turns flow mode on or off.
- Flow End Up/Down Buttons - Set the flow level at full treadle.
- Flow More Information Button - Displays the More Information popup for a detailed view of the settings.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending on the vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup
- Flow/Vacuum Toggle - Switches between Flow Mode and Vacuum Mode.

Forceps Panel (Advanced view only):

- Pressure On/Off Button - Turns Bimanual mode on or off. When Bimanual mode is off the only option is to turn it on. When Bimanual mode is on, the Forceps pressure can be set.
- Pressure Start Up/Down Buttons - Set the pressure at the start of treadle depression.
- Pressure End Up/Down Buttons - Set the pressure at full treadle.
- Forceps More Information Button - Displays the More Information popup.
- Calibration - When the calibration control is turned on, the control changes to one that allows a selection between Start and Close. When Start is selected, the Start pressure is applied to the port, and when Close is selected, the Close pressure is applied to the port. If neither is selected, then no pressure is applied to the port. Pressing the Save Calibration Values button saves the calibrated values.

Vitrectomy: PROPVAC SUBMODE

The Proportional Vacuum (PropVac) submode contains values for maximum vacuum limit and cut-rate set point. As the footpedal is depressed the vacuum increases linearly up to the End limit with the actual vacuum displayed in the Actual Value box and its linear equivalent reflected in the progress bar. The End value can be adjusted using the Up/Down arrow buttons on the vacuum control. Alternatively, selecting the More Information button on the vacuum control displays the More Information popup that has a sidebar for large numeric adjustments in vacuum.

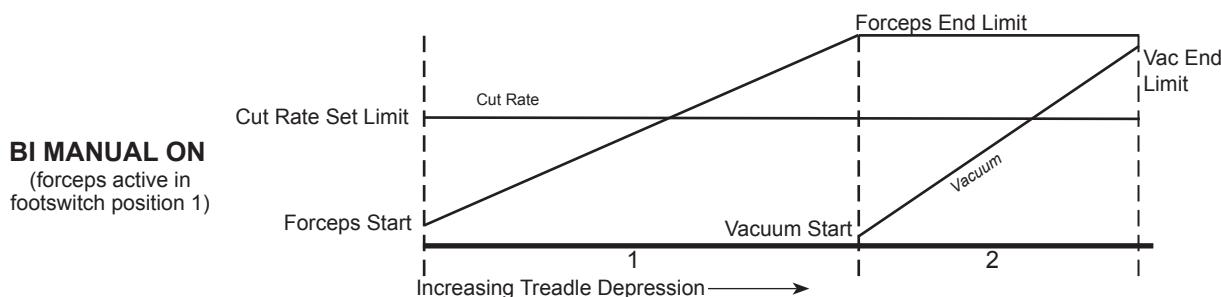
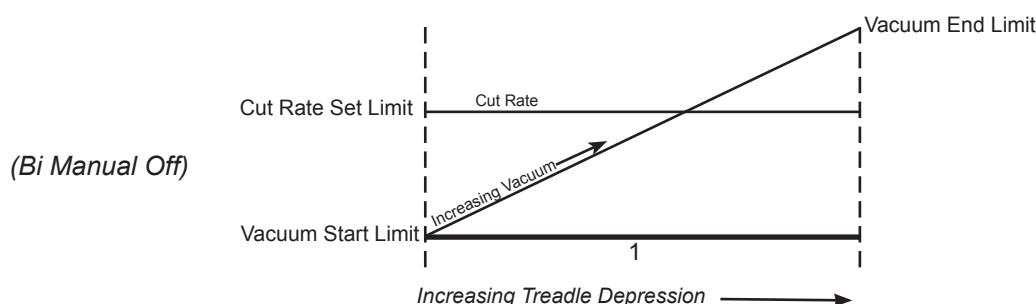
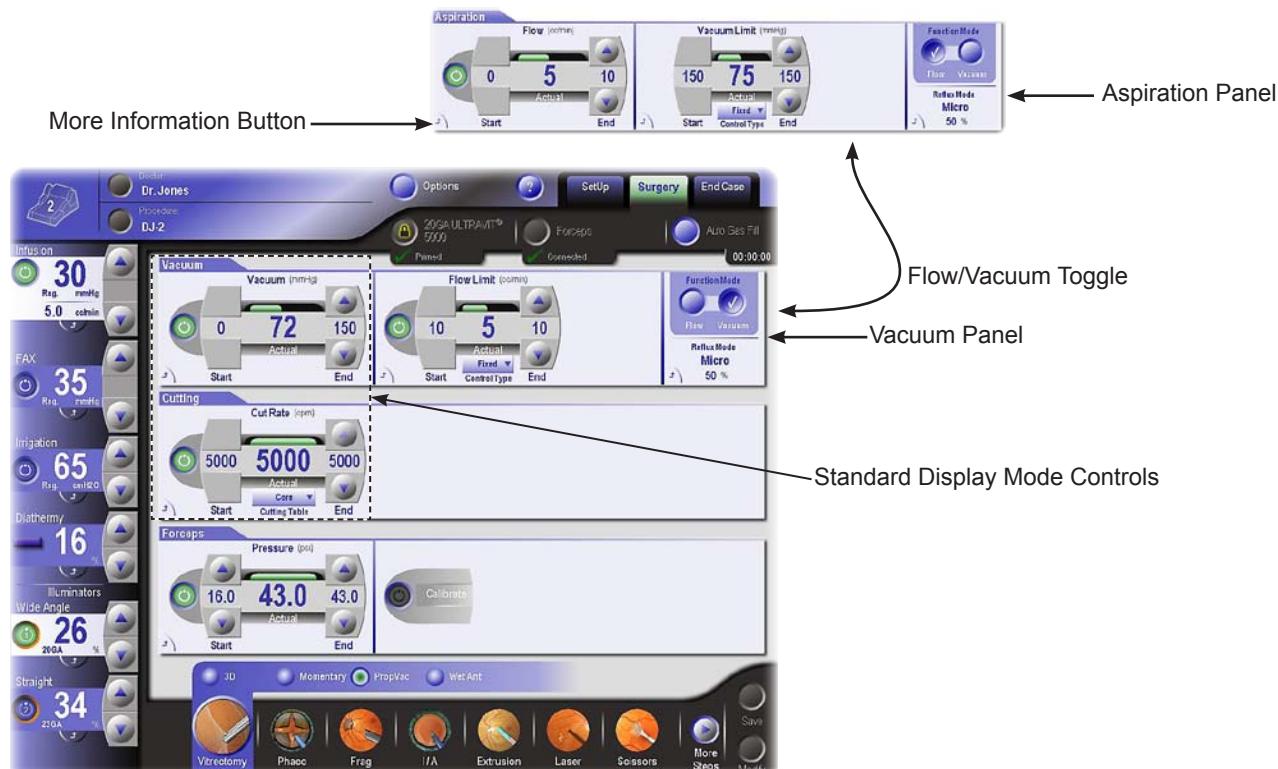


Figure 2-62 Surgery Screen: Vitrectomy Mode-PropVac Submode (Advanced View shown)

Probe cutting at a preset rate begins when the footpedal is pressed. The Cut Rate is adjusted by pressing Up/Down arrow buttons on the Cutting control. Alternatively, selecting the More Information button on the Cutting control displays the More Information popup that has a sidebar for large numeric adjustments in cut rate.

The controls for each panel in PropVac submode are the same as in 3D submode with the following exceptions:

- No Cut Rate Start Up/Down Buttons - Cut rate is a constant rate set by the End buttons and activated when the footpedal is pressed.
- No Vacuum (or Flow) Start Up/Down Buttons.

Vacuum Panel:

- On/Off - Turns vacuum on or off.
- Vacuum End Up/Down Buttons - Set the vacuum level at full treadle.
- Vacuum More Information Button - Displays the More Information popup allowing the user to make changes using slider controls. Also provides panel specific configuration capabilities (such as drainbag change).

The following Vacuum panel controls are available only in the Advanced view:

- Flow Limit On/Off Button - Turns flow limit on or off. When the maximum rate is reached, the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the End value.
- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for the flow rate.
- Flow Limit Configuration Button - Displays the Flow Limit configuration popup.
- Flow/Vacuum Toggle - Switches between Flow Mode and Vacuum Mode.
- Flow Limit Control Type Drop List - Determines whether the flow limit is fixed or linear. In Fixed, the limit is constant regardless of the flow level. In Linear, the limit varies depending on the flow level.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the More Information popup that allows for changing the current mode and the setpoint associated with it.

Cutting Panel:

- Cut Rate On/Off Button - Turns the cutter on or off.
- Cut Rate End Up/Down Buttons - Set the fixed cut rate throughout treadle depression.
- Cutting More Information Button - Displays the More Information popup.
- Cutting Table Drop List (Advanced view only) - Allows selection of port open duty cycle that is appropriate for the procedure to be performed.

Core - Provides the maximum port open duty cycle control suited for core vitrectomy where higher flow rates and efficiency are desirable.

50/50 - Provides a 50% port open duty cycle control for those users who prefer that the cutter is open and closed for the same amount of time.

Shave - Provides the minimum port open duty cycle suited for removing delicate tissue (such as vitreous shaving and membrane dissection) where lower flow rates are desirable.

Aspiration Panel (Flow mode-Advanced view only):

- Flow On/Off Button - Turns flow mode on or off.
- Flow End Up/Down Buttons - Set the flow level at full treadle.
- Flow More Information Button - Displays the More Information popup for a detailed view of the settings.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending on the vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow/Vacuum Toggle - Switches between Flow mode and Vacuum mode.

Forceps Panel (Advanced view only):

- Pressure On/Off Button - Turns Bimanual mode on or off. When Bimanual mode is off, the only option is to turn it on. When Bimanual mode is on, the Forceps pressure can be set.
- Pressure Start Up/Down Buttons - Set the pressure at the start of treadle depression.
- Pressure End Up/Down Buttons - Set the pressure at full treadle.
- Forceps More Information Button - Displays the More Information popup.
- Calibration - When the calibration control is turned on, the control changes to one that allows a selection between Start and Close. When Start is selected, the Start pressure is applied to the port, and when Close is selected, the Close pressure is applied to the port. If neither is selected, then no pressure is applied to the port. Pressing the Save Calibration Values button saves the calibrated values.

Vitrectomy: WETANT SUBMODE

In WetAnt submode, the irrigation and cut rate are fixed while the user has linear footswitch control of the vacuum. The footswitch has two ranges. The first range has fixed irrigation only while the second range activates a fixed cut rate and linear vacuum that increases with treadle depression (see graphic in Figure 2-63). In Advanced Display mode, the Flow Limit Control Type can be changed.

The Cut Rate is adjusted by pressing Up/Down arrow buttons on the Cutting control. Alternatively, selecting the More Information button on the Cutting control displays the More Information popup that has a sliderbar for large numeric adjustments in cut rate.

The controls for each panel in WetAnt submode are the same as in 3D submode with the following exceptions:

- No Vacuum On/Off Button.
- No Cut Rate Start Up/Down Buttons - Cut rate is a constant rate set by the End buttons and activated when the footpedal is pressed.
- No Forceps Panel.
- No Vacuum (or Flow) Start Up/Down Buttons.

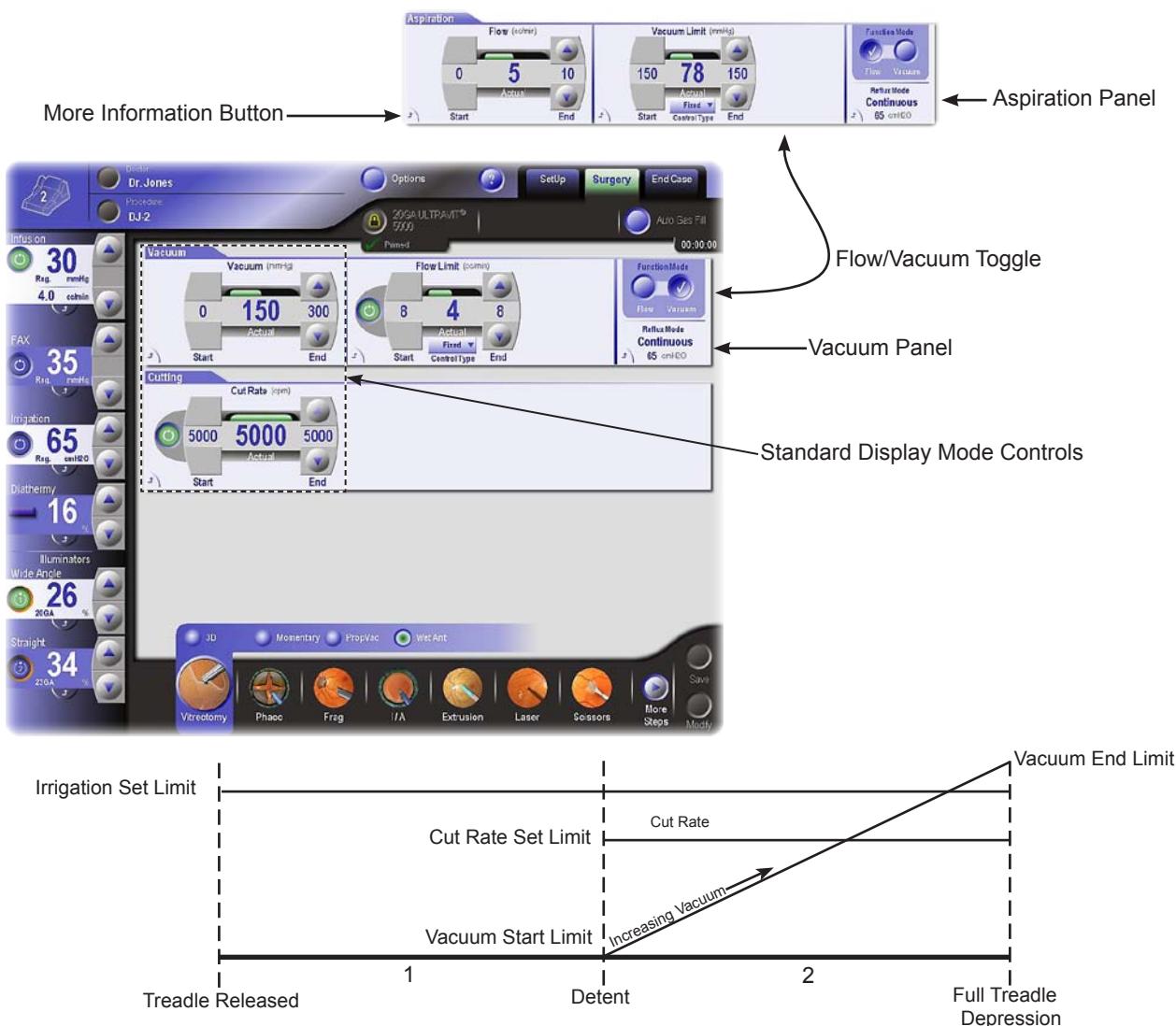


Figure 2-63 Surgery Screen: Vitrectomy Mode-WetAnt Submode (Advanced View shown)

Vacuum Panel:

- Vacuum End Up/Down Buttons - Set the vacuum level at full treadle.
- Vacuum More Information Button - Displays the More Information popup allowing the user to make changes using slider controls. Also provides panel specific configuration capabilities (such as drainbag change).

The following Vacuum panel controls are available only in the Advanced view:

- Flow Limit On/Off Button - Turns flow limit on or off. When the maximum rate is reached the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the End value.
- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for flow rate.
- Flow Limit More Information Button - Displays the Flow Limit More Information popup.
- Flow/Vacuum Toggle - Switches between Flow mode and Vacuum mode.
- Flow Limit Control Type Drop List - Determines whether the flow limit is fixed or linear. In Fixed, the limit is constant regardless of the flow level. In Linear, the limit varies depending on the flow level.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the More Information popup that allows for changing the current mode and the setpoint associated with it.

Cutting Panel:

- Cut Rate On/Off Button - Turns the cutter on or off.
- Cut Rate End Up/Down Buttons - Set the cut rate at full treadle.
- Cutting More Information Button - Displays the More Information popup.

Aspiration Panel (Flow mode-Advanced view only):

- Flow End Up/Down Buttons - Set the flow level at full treadle.
- Flow More Information Button - Displays the More Information popup for a detailed view of the settings.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending on the vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow/Vacuum Toggle - Switches between Flow mode and Vacuum mode.

Vitrectomy: VITDRY SUBMODE (available only when an anterior cassette is installed)

In the VitDry submode, the cut rate is fixed while the user has linear footswitch control of the vacuum through the full range of treadle motion (see graphic in Figure 2-64). In Advanced Display mode, the Flow Limit Control Type can be changed.

The Cut Rate is adjusted by pressing Up/Down arrow buttons on the Cutting control. Alternatively, selecting the More Information button on the Cutting control displays the More Information popup that has a sliderbar for large numeric adjustments in cut rate.

The controls for each panel in VitDry submode are the same as in 3D submode with the following exceptions:

- No Vacuum On/Off Button.
- No Cut Rate Start Up/Down Buttons - Cut rate is a constant rate set by the End buttons and activated when the footpedal is pressed.
- No Forceps Panel.
- No Vacuum (or Flow) Start Up/Down Buttons.

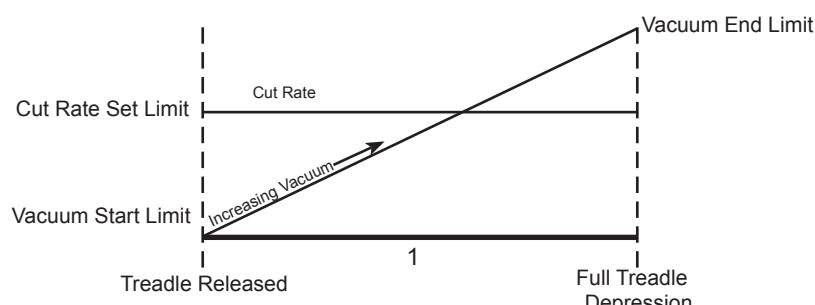
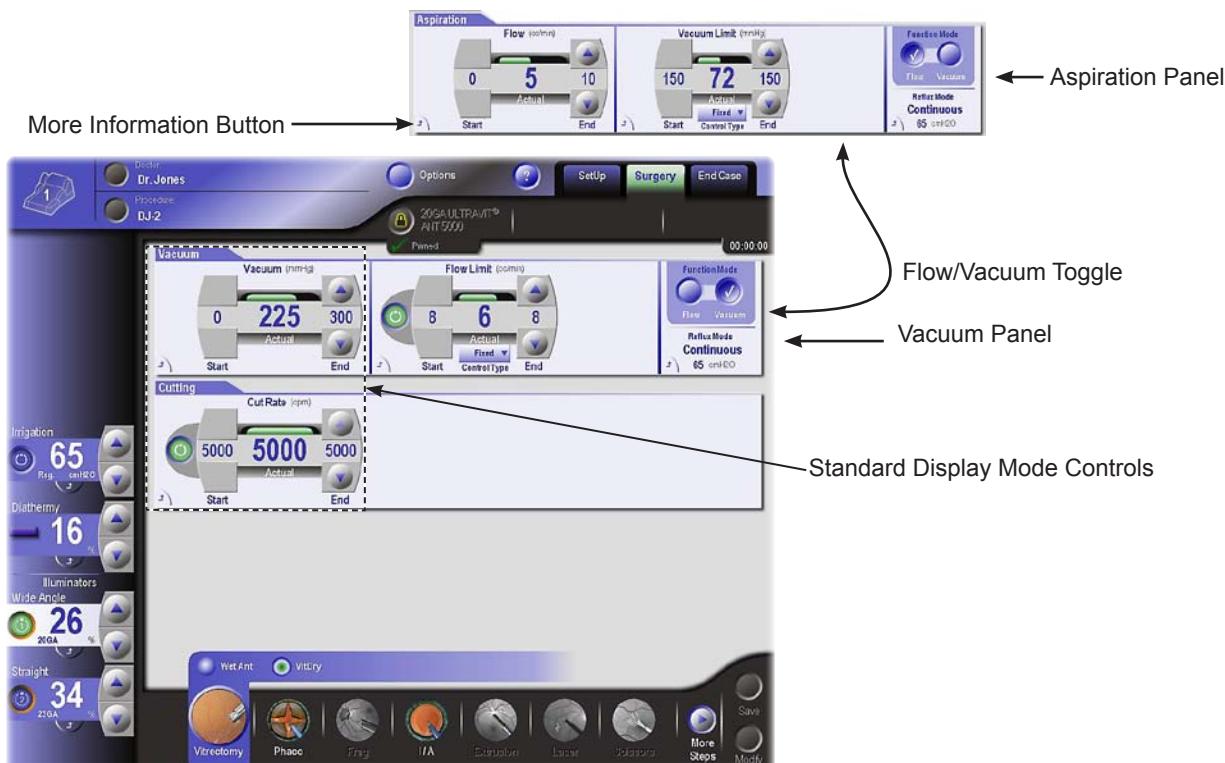


Figure 2-64 Surgery Screen: Vitrectomy Mode-VitDry Submode (Advanced View shown)

Vacuum Panel:

- Vacuum End Up/Down Buttons - Set the vacuum level at full treadle.
- Vacuum More Information Button - Displays the More Information popup allowing the user to make changes using slider controls. Also provides panel specific configuration capabilities (such as drainbag change).

The following Vacuum panel controls are available only in the Advanced view:

- Flow Limit On/Off Button - Turns flow limit on or off. When the maximum rate is reached the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the End value.
- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for flow rate.
- Flow Limit More Information Button - Displays the Flow Limit More Information popup.
- Flow/Vacuum Toggle - Switches between Flow mode and Vacuum mode.
- Flow Limit Control Type Drop List - Determines whether the flow limit is fixed or linear. In Fixed, the limit is constant regardless of the flow level. In Linear, the limit varies depending on the flow level.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the More Information popup that allows for changing the current mode and the setpoint associated with it.

Cutting Panel:

- Cut Rate On/Off Button - Turns the cutter on or off.
- Cut Rate End Up/Down Buttons - Set the cut rate at full treadle.
- Cutting More Information Button - Displays the More Information popup.

Aspiration Panel (Flow mode-Advanced view only):

- Flow End Up/Down Buttons - Set the flow level at full treadle.
- Flow More Information Button - Displays the More Information popup for a detailed view of the settings.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed, the limit is constant regardless of the vacuum level. In Linear, the limit varies depending on the vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow/Vacuum Toggle - Switches between Flow mode and Vacuum mode.

PHACO MODE

Phaco mode provides phacoemulsification capabilities by using U/S (ultrasound) powered handpieces controlled by the footswitch. Phaco power is defined as being proportional to ultrasound displacement of the phaco tip. Amplitude of the ultrasound displacement of the phaco tip is proportional to the ultrasound power displayed on the console front panel.

When the U/S handpiece is selected, irrigation, aspiration, and phaco power are provided to the handpiece tip. Phaco power is defined as being proportional to ultrasound displacement of the phaco tip. Amplitude of the ultrasound displacement of the phaco tip is proportional to the ultrasound power displayed on the console front panel. The user has the ability to adjust the aspiration rate, vacuum levels, and phaco power at any time during the surgical procedure via their respective adjustment arrows or remote control.

The phaco Power Limit is increased or decreased via the front panel in increments of 5% from a minimum of 0% to a maximum of 100%. The amount of phaco power delivered to the handpiece is controlled by one of two methods: linear or fixed footpedal control.

In Flow mode, the Aspiration panel is displayed, while in Vacuum mode, the Vacuum panel is displayed. In "Standard" display mode, only the Vacuum mode controls are available. When system detects an occlusion in Flow mode, an alarm sounds and the word "Occlusion" appears on the extraction panel under the primary limit control's label.

WARNING!

Good clinical practice dictates testing for adequate irrigation, aspiration flow, reflux, and operation as applicable for each handpiece prior to entering eye.

The five submodes available in Phaco mode are listed below. In each submode, the Aspiration and Vacuum panels are identical while the Ultrasound panels change according to the requirements of the current mode.

- 3D
- Burst
- Custom (Advanced View only)
- Pulsed
- Continuous

Dynamic Rise

The value in the display bar indicates the current rise time for the aspiration pump rate adjustment at occlusion onset. The Dynamic Rise setting can vary from -2 to 4, in increments of 1. When Dynamic Rise -2 is displayed in the Adjust Bar, it indicates that the rise time in aspiration pump rate adjustment is slowest. When Dynamic Rise 4 is displayed in the Adjust Bar, it indicates that the rise time in aspiration pump rate adjustment is fastest. The Alcon default setting is 0. Dynamic rise is only available in Flow Mode.

WARNING!

The use of Dynamic Rise setting 1, 2, 3, or 4 may result in aspiration levels (volumes) exceeding irrigation flow. This may cause chamber shallowing or collapse which may result in patient injury.

Smart Pulse

If the duration of the ultrasound pulse becomes less than 20 ms, a proprietary algorithm becomes active. This is indicated by the Smart Pulse message appearing on the screen below the Power bar as shown in Figure 2-65.

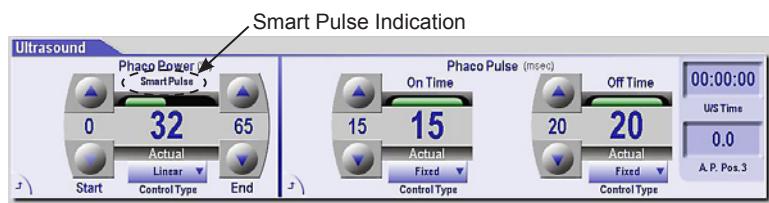
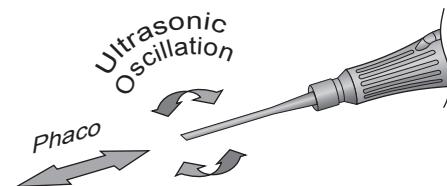


Figure 2-65 Smart Pulse Indication

When the algorithm is active, ultrasound power will be generated at 10% or half of the commanded power, whichever is lower, prior to the application of the main power pulse. This low-powered pulse contributes a negligible amount of energy to the procedure, but it allows the electronic equipment to determine the optimum operating parameters for the main power pulse, thus making it more efficient, even for the shortest duration of ultrasound. The Smart Pulse algorithm can be active in Custom, Pulsed, or Continuous modes when used with the OZil® torsional or U/S handpieces. The minimum duration of the main pulse in ultrasound is 5 ms; the minimum duration of torsional pulse is 20 ms.

OZil® Mode of Operation

When the *OZil®* torsional handpiece is selected, irrigation, aspiration, phaco power and ultrasonic oscillations are provided by the handpiece. In this mode of operation phaco power and ultrasonic oscillations alternately turn on and off. Amplitude of the ultrasound and torsional displacement of the phaco tip are proportional to the ultrasound power and torsional amplitude displayed on the console front panel. The user has the ability to adjust the aspiration rate, vacuum levels, phaco power, and torsional amplitude (ultrasonic oscillations) at any time during the surgical procedure via their respective adjustment arrows or remote control. For best performance of the *OZil®* torsional handpiece, use tips recommended by your Alcon representative.



OZil® Power/Amplitude

The Phaco Power Limit and Torsional Amplitude Limit are increased or decreased via the front panel in increments of 5% from a minimum of 0% to a maximum of 100%. Power/Amplitude to the handpiece is controlled by one of two methods: linear or fixed footpedal control (except 3D mode which is always linear).

- **Linear Footpedal Control** - If linear (increasing) footpedal control is selected, the Limit buttons indicate the maximum phaco power and ultrasonic oscillations (Torsional Amplitude) delivered with the footpedal fully depressed. In footpedal position 3 (position 2 for 3D mode), power and oscillations start at the start limit and change linearly until power reaches the end limit at full footpedal depression.

- Fixed Footpedal Control - If fixed footpedal control is selected, the Limit buttons indicate the phaco power and ultrasonic oscillations delivered throughout footpedal position 3. To increase or decrease power, the arrow buttons must be pressed.

OZil® Timing

Phaco power and ultrasonic oscillations are delivered to the phaco tip through a variety of timing configurations when in footpedal position 3 (position 2 for 3D mode). Depending on the mode selected, the timing can be continuous or can include off-times between phaco/torsional pulses.

Phaco Mode: 3D SUBMODE

In Phaco 3D submode, vacuum and U/S power delivered to the probe are simultaneously regulated by the amount of footpedal depression. The display contains adjustable values for vacuum level at treadle start and at full depression; and U/S power at treadle start and at full depression.

To prevent generating excessive flow when the footpedal is first depressed, the vacuum level is ramped up from zero to the set starting level during the first part of the pedal travel. The Ramping % is selected in the Doctor's Settings screen with an available range of 15-90%.

The 3D submode screen is shown in Figure 2-66 along with a graphic representation of the functions in each footswitch treadle position. Note that the start and end limits for both U/S Power and vacuum are adjustable therefore any combination of limits is valid. The graphic shows only one possibility.

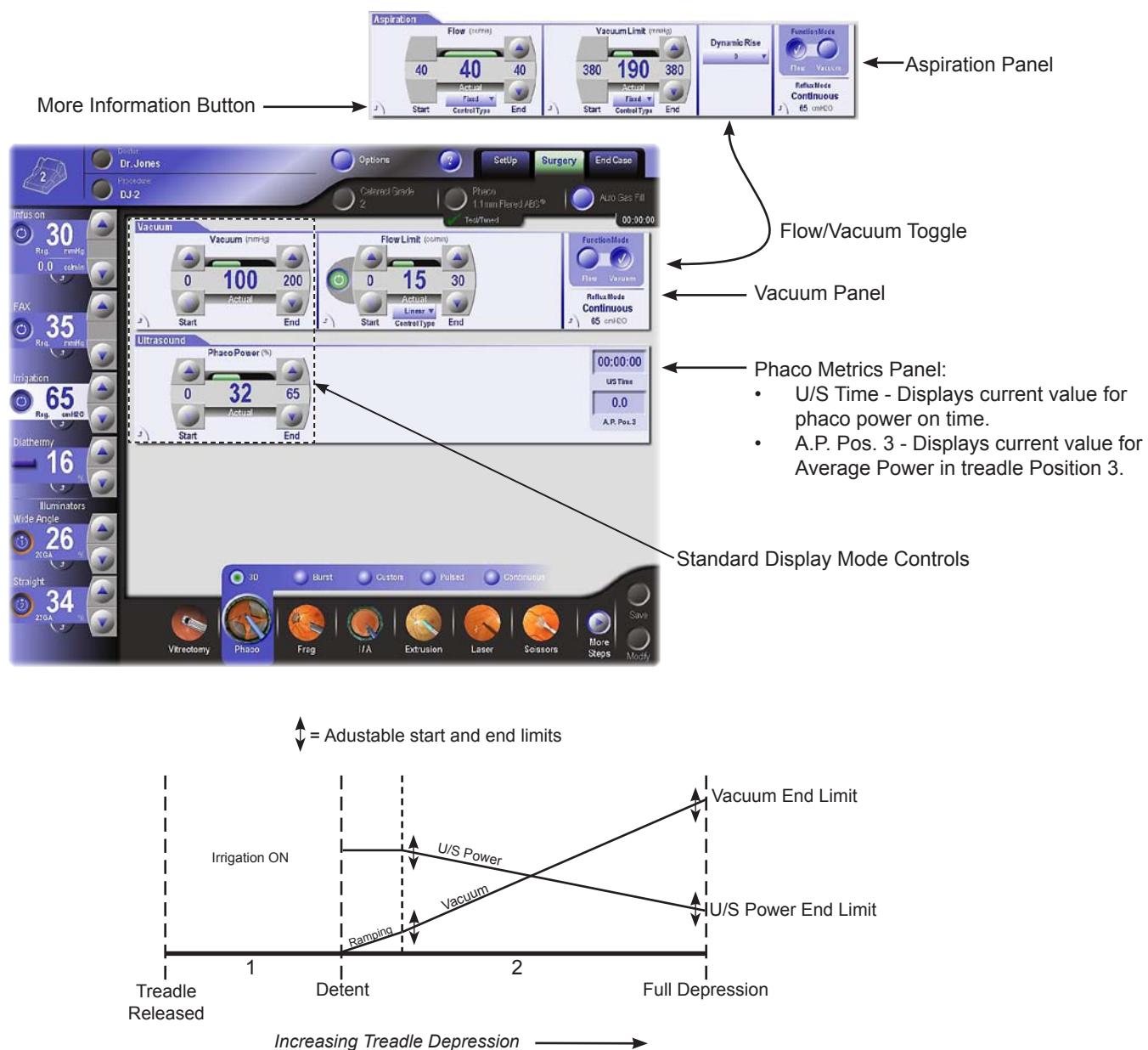


Figure 2-66 Surgery Screen: Phaco Mode-3D Submode (Advanced View shown)

The controls for each panel in 3D submode have the following functions:

Vacuum Panel:

- Vacuum Start Up/Down Buttons - Set the vacuum level at treadle start of position 2.
- Vacuum End Up/Down Buttons - Set the vacuum level at full treadle.
- Vacuum More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls. Also provides the capability to initiate a drainbag change.

The following vacuum controls are available only in the Advanced View:

- Flow Limit On/Off Button - Turns Flow Limit on or off. When the maximum rate is reached, the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the Start and End values.
- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for flow rate.
- Flow Limit Progress Bar and Numerical Value - Show the current flow level.
- Flow Limit More Information Button - Displays the More Information popup.
- Flow Limit Control Type Drop List - Determines whether the flow limit is fixed or linear. In Fixed the limit is constant regardless of the flow level. In Linear the limit varies depending on the flow level.
- Flow/Vacuum Toggle - Switches between Flow Mode and Vacuum Mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Aspiration Panel (This control is available only in the Advanced view by switching the Function Mode from Vacuum to Flow):

- Flow Control Type Drop List - Determines whether the flow is fixed or linear.
- Flow Start Up/Down Buttons - If Linear control is selected, these buttons set the flow level at treadle start. If Fixed control is selected, they are not active.
- Flow End Up/Down Buttons - If Linear control is selected, these buttons set the flow level at full treadle. If Fixed control is selected, they set the fixed flow level.
- Dynamic Rise Drop List - Selects the rise value. The rise value determines the slope of the increase applied.
- Flow More Information Button - Displays the More Information popup which simplifies large value changes by providing slider controls. Also provides the capability to initiate a drainbag change.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending treadle depression.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow/Vacuum Toggle: Switches between Flow mode and Vacuum mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Ultrasound Panel:

- Phaco Power Start Up/Down Buttons - Set the power level at treadle start (of position 3).
- Phaco Power End Up/Down Buttons - Set the power at full treadle.
- Phaco Power Progress Bar and Numerical Value - Show the current power value.
- Ultrasound More Information Button - Displays the More Information popup.

Phaco Mode: 3D SUBMODE - OZIL® 3D

When an *OZIL®* handpiece is connected to the system, the 3D ultrasound panel will appear as shown in Figure 2-67. Start and End limits for both Phaco power and Torsional amplitude are adjustable by the user. In footswitch position 2, phaco power and torsional amplitude will increase/decrease linearly from start limit to the end limit according to the limits selected.

When the Phaco Power default setting is set to 0 (no phaco power), then only torsional ultrasonic oscillations at the preset Torsional Amplitude are delivered, for 100% of the time, to the handpiece tip. This allows the user to have continuous torsional ultrasonic oscillations if so desired. If U/S power is added, then this mode of operation provides 20% of its duty cycle for phaco power, then torsional ultrasonic oscillations for the remaining 80% when in footpedal position 2, and repeats this cycle over and over again as long as the footpedal is in position 2. This produces continuous U/S alternations between phaco power and torsional amplitude.

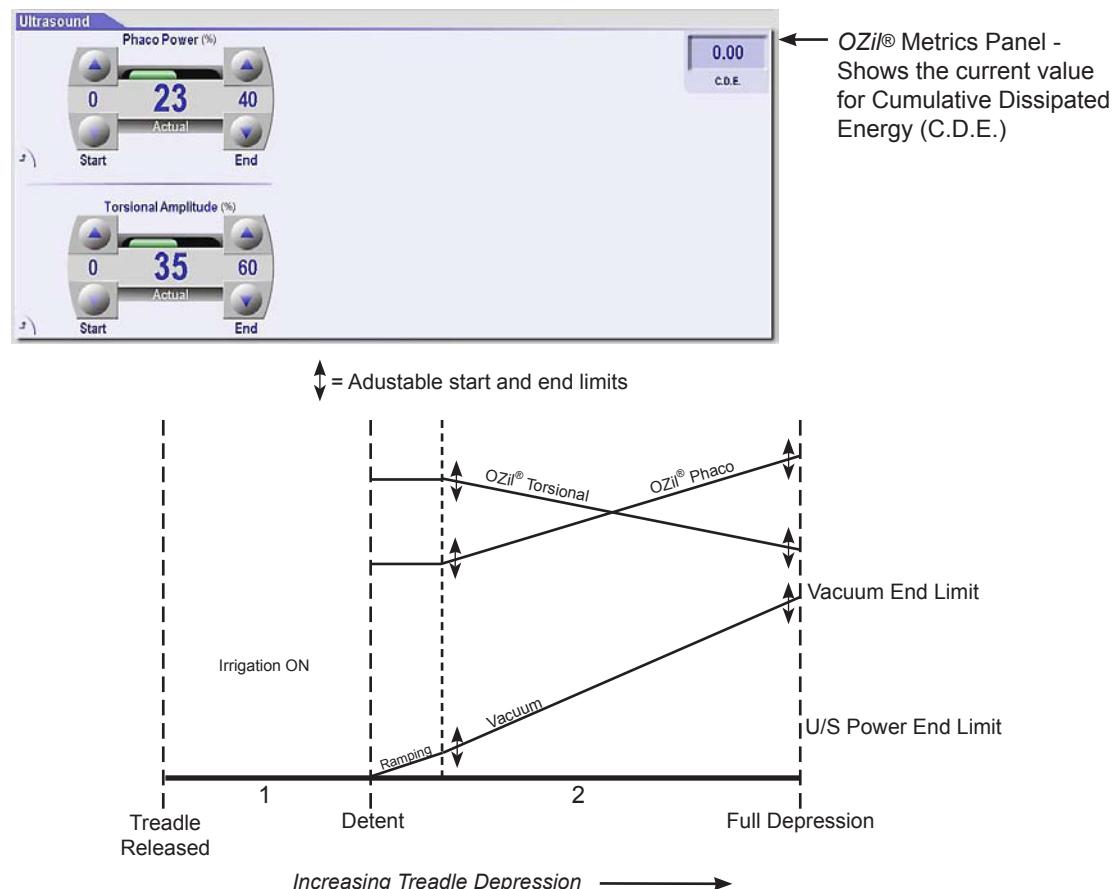


Figure 2-67 Surgery Screen: Phaco Mode - 3D Submode- OZIL® 3D

Phaco Mode: BURST SUBMODE

In the Phaco Burst submode, fixed U/S power (Power %) can be adjusted for duration (On Time) and time off between (Off Time) U/S power pulses. The frequency of bursts is controlled with the footpedal from detent two to full treadle depression, while the fixed burst length is set in milliseconds (msec). The actual percent of time U/S power is activated is reflected in the Actual window.

The controls for each panel in Burst submode (see Figure 2-68) have the following functions:

Vacuum Panel:

- Vacuum End Up/Down Buttons - Set the vacuum level at the end of position 2.
- Vacuum Start Up/Down Buttons - Set the vacuum level at the start of treadle position 2.
- Vacuum More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls. Also provides the capability to initiate a drainbag change.

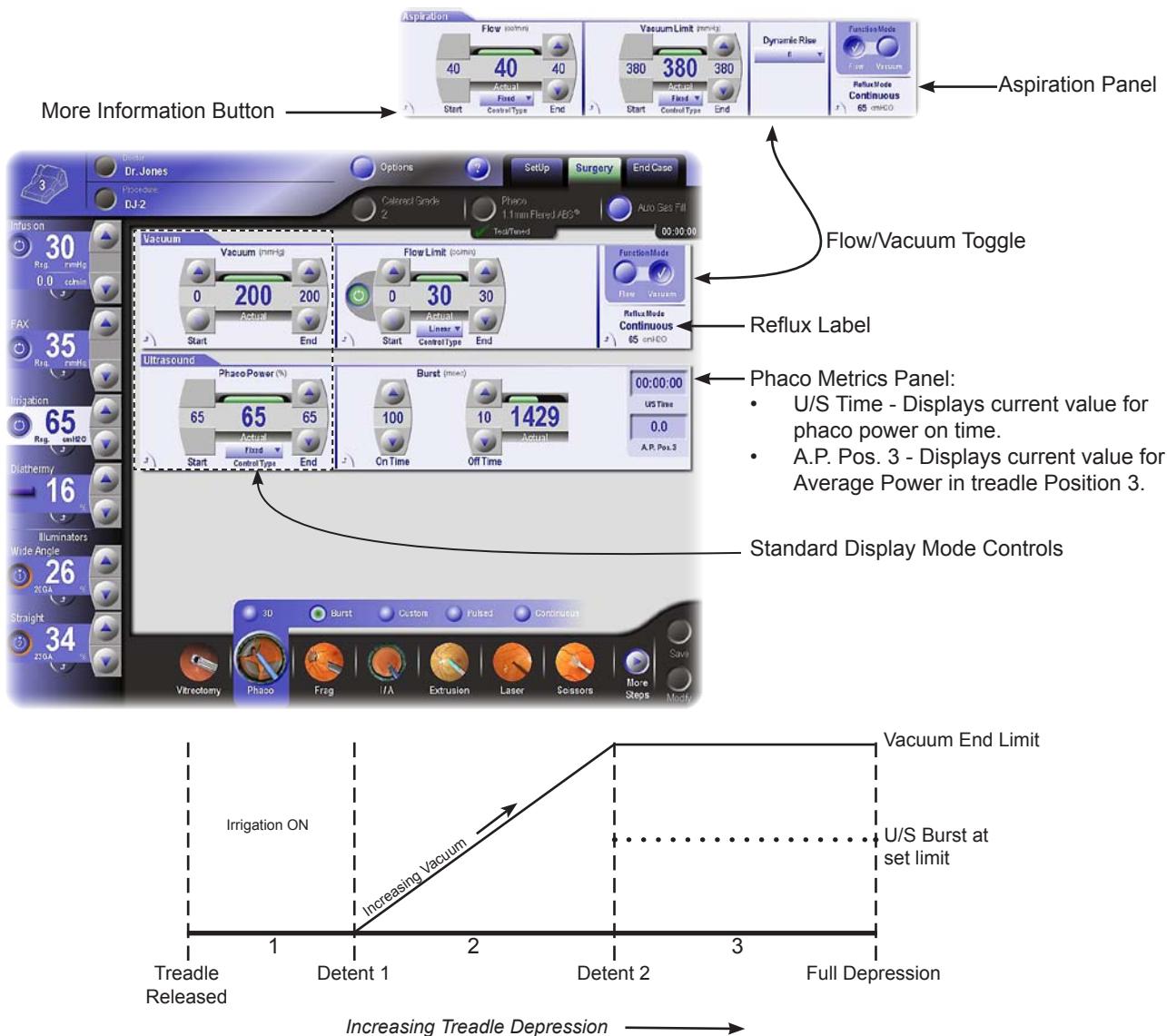


Figure 2-68 Surgery Screen: Phaco Mode - Burst Submode (Advanced View shown)

The following vacuum controls are available only in the Advanced View:

- Flow Limit On/Off Button - Turns Flow Limit on or off. When the maximum rate is reached, the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the Start and End values.
- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for flow rate.
- Flow Limit Progress Bar and Numerical Value - Show the current flow level.
- Flow Limit More Information Button - Displays the More Information popup.
- Flow Limit Control Type Drop List - Determines whether the flow limit is fixed or linear. In Fixed the limit is constant regardless of the flow level. In Linear the limit varies depending on the flow level.
- Flow/Vacuum Toggle - Switches between Flow Mode and Vacuum Mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Aspiration Panel (This control is available only in the Advanced view by switching the Function Mode from Vacuum to Flow):

- Flow Start Up/Down Buttons - When linear, set Flow at treadle start of position 2.
- Flow End Up/Down Buttons - Set the flow level at end of position 2.
- Dynamic Rise Drop List - Selection for the rise value. The rise value determines the automatic adjustment of the flow set point when occlusion onset is reached.
- Flow More Information Button - Displays the More Information popup which simplifies large value changes by providing slider controls. Also provides the capability to initiate a drainbag change.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending on the vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow/Vacuum Toggle: Switches between Flow mode and Vacuum mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Ultrasound Panel:

- Power Start Up/Down Buttons - When Linear, set power at start of position 3.
- Power End Up/Down Buttons - Set the power at full treadle.
- Power Progress Bar and Numerical Value - Displays the current power value.
- Power Limit Control Type Drop List (*Advanced view only*) - Determines whether the power is fixed or linear. In Fixed, the power is constant. In Linear, the power varies depending on the treadle position.
- Phaco Power More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls.
- Phaco Burst On Time Up/Down Buttons - Set the Phaco Burst On time.
- Phaco Burst Off Time Up/Down Buttons - Set the Phaco Burst Off time.
- Phaco Burst Off Time Progress Bar and Numeric Value - Shows the current Phaco Burst Off time.
- Phaco Burst More Information Button - Displays the More Information popup.

Phaco Mode: BURST SUBMODE - *OZiL® BURST*

When operating in this mode, phaco burst is followed immediately by torsional burst, followed by an off-time. Duration of the phaco burst is determined by the setting on the panel, for example 35 ms in the Figure 2-69; duration of the torsional burst is 70 ms. Duration of the off-time is determined by the footpedal in position 3. At the beginning it is equal to 2500 ms, and is gradually reduced as the footpedal is depressed. When the footpedal is depressed all the way, the off-time will be equal to that set on the panel – 10 ms in the given example.

If Phaco Power Limit and/or Torsional Amplitude Limit are set to zero, then there are no phaco or torsional contributions to the *OZiL®* burst, and the duty cycles (On ms) are not adjustable.

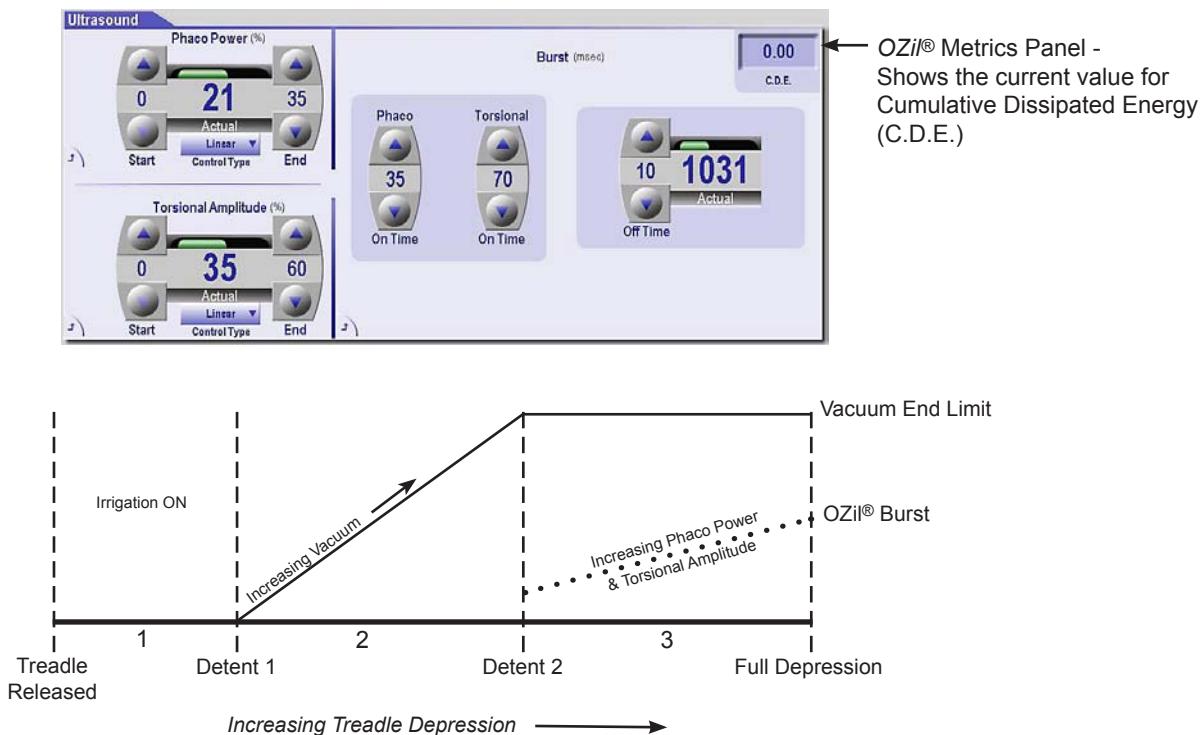


Figure 2-69 **Surgery Screen: Phaco Mode: Burst Submode - *OZiL®* Burst**

Phaco Mode: CUSTOM SUBMODE

The Custom submode is only available in the Advanced view.

In the Phaco Custom submode fixed or linear U/S power (Power %) can be adjusted for duration (On Time) and time off between (Off Time) U/S power pulses. The frequency of bursts is controlled with the footpedal from detent two to full treadle depression, while the fixed burst length is set in milliseconds (msec). The actual percent of time U/S power is activated is reflected in the Actual window. The controls for each panel in Custom submode have the following functions:

Vacuum Panel:

- Vacuum Start Up/Down Buttons - Set the vacuum level at the start of treadle position 2.
- Vacuum End Up/Down Buttons - Set the vacuum level at the end of treadle position 2.
- Vacuum More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls. Also provides the capability to initiate a drainbag change.

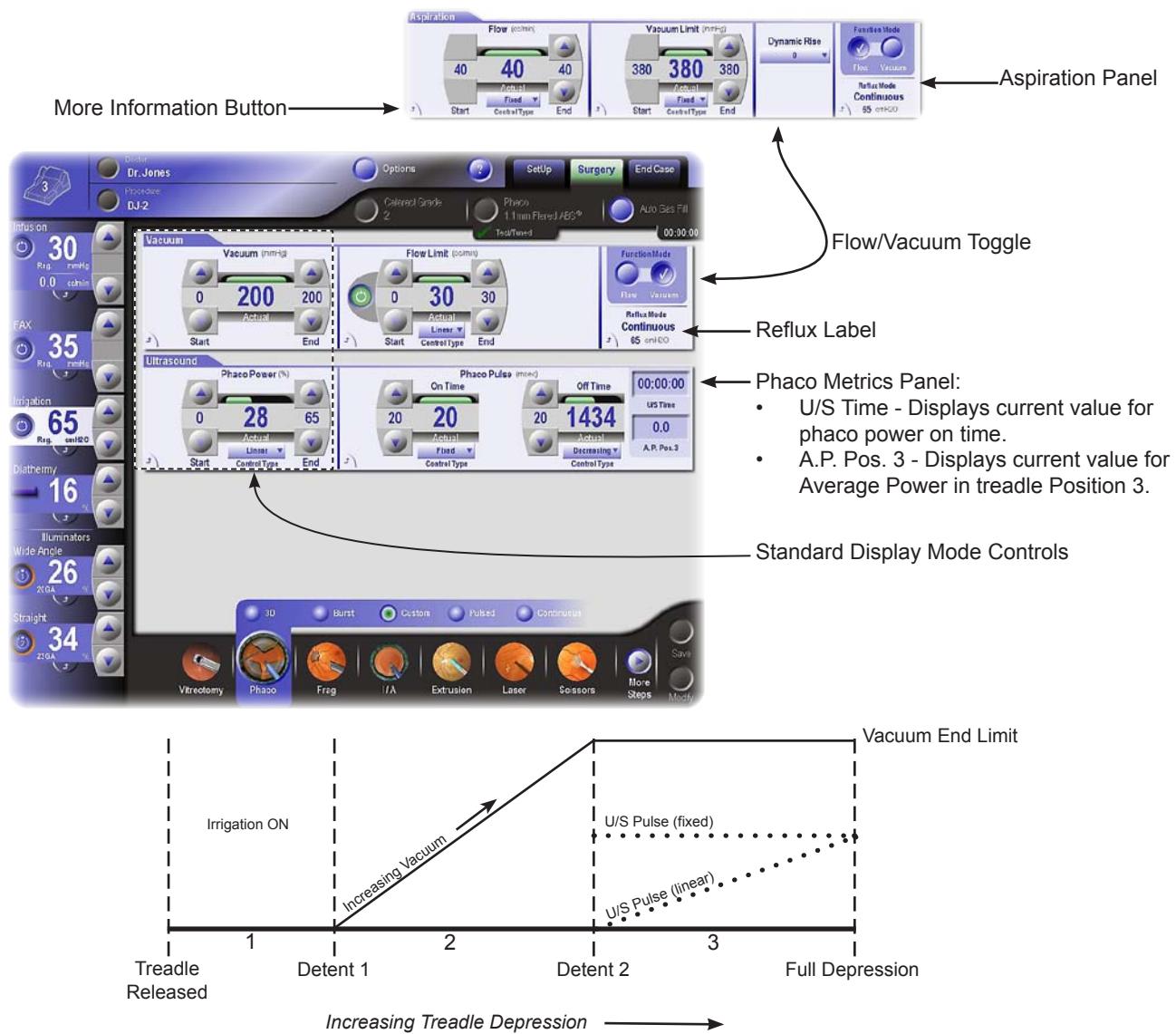


Figure 2-70 Surgery Screen: Phaco Mode - Custom Submode (Advanced view shown)

The following vacuum controls are available only in the Advanced View:

- Flow Limit On/Off Button - Turns Flow Limit on or off. When the maximum rate is reached, the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the Start and End values.
- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for flow rate.
- Flow Limit Progress Bar and Numerical Value - Show the current flow level.
- Flow Limit More Information Button - Displays the More Information popup.
- Flow Limit Control Type Drop List - Determines whether the flow limit is fixed or linear. In Fixed, the limit is constant regardless of the flow level. In Linear, the limit varies depending on the flow level.
- Flow/Vacuum Toggle - Switches between Flow mode and Vacuum mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Aspiration Panel (This control is available only in the Advanced view by switching the Function Mode from Vacuum to Flow):

- Flow Start Up/Down Buttons - When linear, set the flow level at start of position 2.
- Flow End Up/Down Buttons - Set the flow level at the end of position 2.
- Dynamic Rise Drop List - Select for the rise value. The rise value determines the automatic adjustment of the flow set point when occlusion onset is reached.
- Flow More Information Button - Displays the More Information popup which simplifies large value changes by providing slider controls. Also provides the capability to initiate a drainbag change.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending on the vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow/Vacuum Toggle: Switch between Flow mode and Vacuum mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Ultrasound Panel:

- Phaco Power Start Up/Down Buttons - When linear, set power at start of position 3.
- Phaco Power End Up/Down Buttons - Set the power at full treadle.
- Phaco Power Progress Bar and Numerical Value - Show the current power value.
- Phaco Power Limit Control Drop Down List - Determines whether the power is fixed or linear. In Fixed the power is constant regardless. In Linear the power varies depending on the treadle position.
- Phaco Power More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls.
- Phaco Pulse On Time Up/Down Buttons - Set the Phaco pulse on time.
- Phaco Pulse On Time Progress Bar and Numeric Value - Show the current Phaco pulse on time.
- Phaco Pulse On Time Limit Control Drop Down List - Determines whether the pulse on time pulse type limit is decreasing, fixed, or increasing. In Fixed, the Pulse On Time is constant. In Decreasing, the Pulse On Time is decreased as the

treadle is pressed downward. In Increasing, the Pulse On Time is increased as the treadle is pressed downward.

- Phaco Pulse Off Time Up/Down Buttons - Set the Phaco pulse off time.
- Phaco Pulse Off Time Progress Bar and Numeric Value - Show the current Phaco pulse off time.
- Phaco Pulse Off Time Control Drop Down List - Determines whether the pulse off time pulse type limit is decreasing or fixed. In Decreasing, the Pulse Off Time is decreased as the treadle is pressed downward. In Fixed, the Pulse Off Time is constant.
- Phaco Pulse More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls.
- Smart Pulse Indicator - Displayed when U/S power is greater than zero and pulse on time is less than 20 ms.

Phaco Mode: CUSTOM SUBMODE - OZIL® CUSTOM PULSE

When operating in this mode, phaco power and ultrasonic oscillations are turned on and off for a period of time determined by the user and the position of the footswitch in position 3. The system repeats this sequence of events: phaco power on then off-time, ultrasonic oscillations on then off-time. This screen is only available in the Advanced View.

- The on-time can be fixed at the selected setting throughout position 3, set to increase at the beginning of position 3 to the set limit at the end of position 3, or set to decrease from the set limit at the beginning of position 3 down to the set limit at the end of position 3.
- The off-time can be fixed at the selected setting throughout position 3, or set to decrease from 2500 ms at the beginning of position 3 down to the set limit at the end of position 3. When not in footpedal position 3 the user setting is displayed; when in position 3 the actual value is displayed.

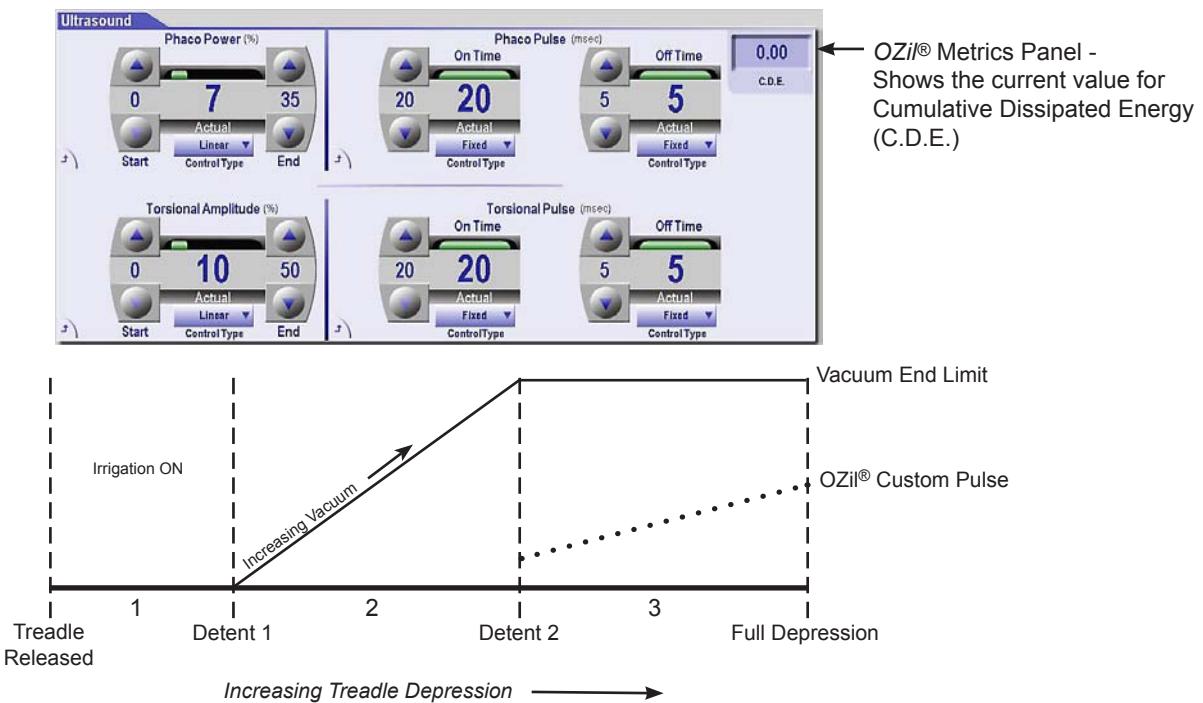


Figure 2-71 **Surgery Screen: Phaco Mode - Custom Submode - OZIL® Custom Pulse (Advanced view shown)**

Phaco Mode: PULSED SUBMODE

In the Phaco Pulsed submode, fixed or linear U/S power (Power %) can be adjusted for Rate (pulses per second-pps) and Time On (%) U/S power pulses. The pulse is controlled with the footpedal from detent two to full treadle depression. The actual percent of time U/S power is activated is reflected in the Actual window.

The controls for each panel in Pulsed submode have the following functions:

Vacuum Panel:

- Vacuum Start Up/Down Buttons - Set the vacuum level at the start of treadle position 2.
- Vacuum End Up/Down Buttons - Set the vacuum level at the end of treadle position 2.
- Vacuum More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls. Also provides the capability to initiate a drainbag change.

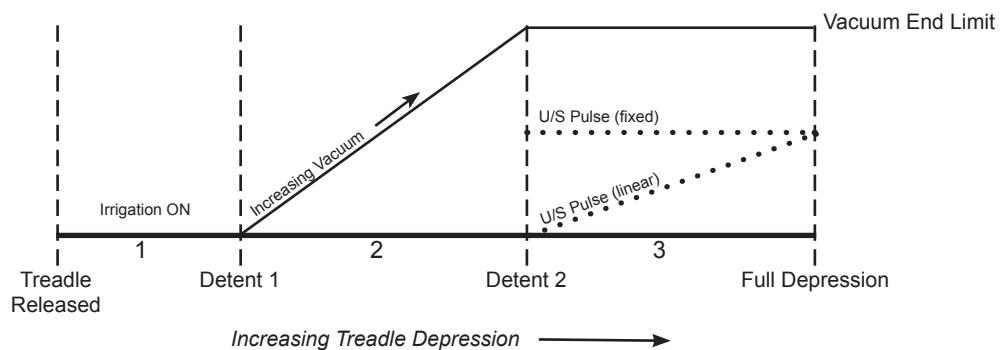
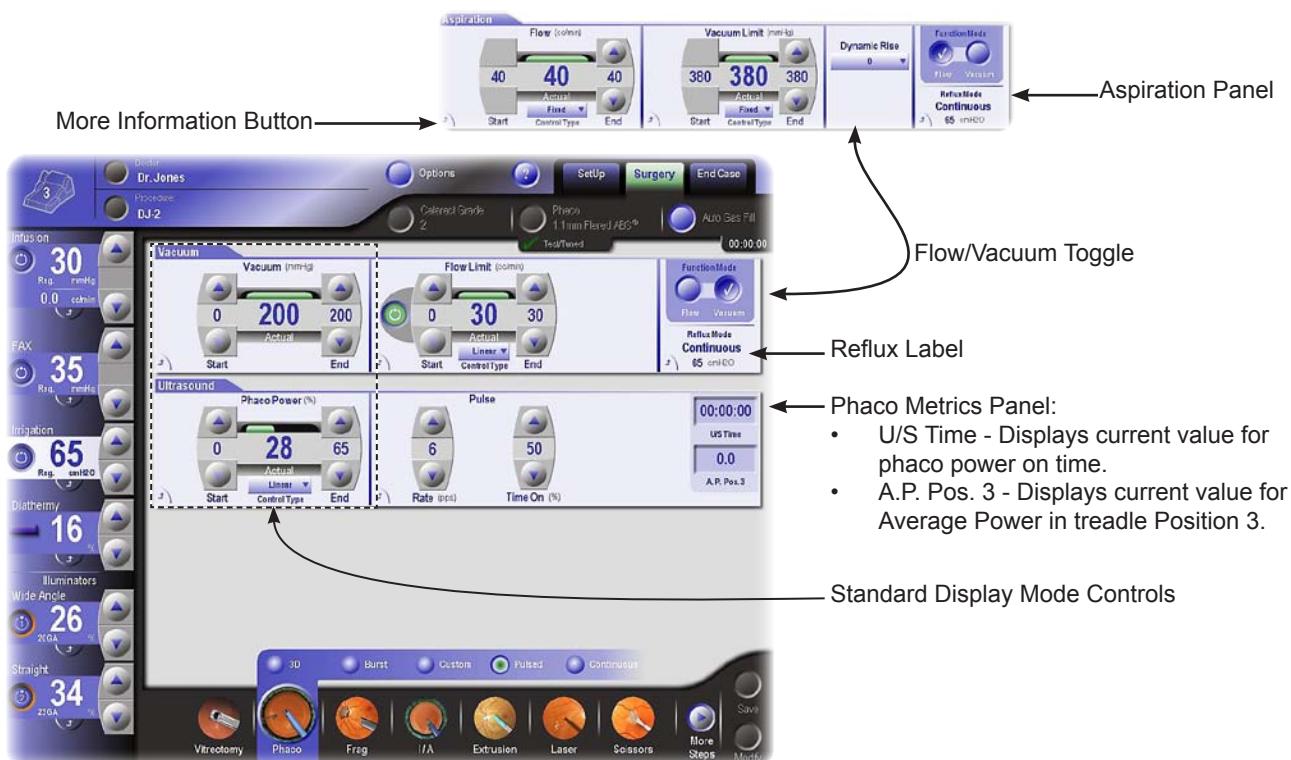


Figure 2-72 Surgery Screen: Phaco Mode - Pulsed Submode (advanced view shown)

The following vacuum controls are available only in the Advanced View:

- Flow Limit On/Off Button - Turns Flow Limit on or off. When the maximum rate is reached, the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the Start and End values.
- Flow Start and End Up/Down Buttons - Set the start and end limits for flow rate.
- Flow Limit Progress Bar and Numerical Value - Shows the current flow level.
- Flow Limit More Information Button - Displays the More Information popup.
- Flow Limit Control Type Drop List - Determines whether the flow limit is fixed or linear. In Fixed the limit is constant regardless of the flow level. In Linear the limit varies depending on the flow level.
- Flow/Vacuum Toggle - Switches between Flow Mode and Vacuum Mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Aspiration Panel (This control is available only in the Advanced view by switching the Function Mode from Vacuum to Flow):

- Flow Start Up/Down Buttons - When linear, set flow at treadle start in position 2.
- Flow End Up/Down Buttons - Set the flow level at end of treadle position 2.
- Dynamic Rise Drop List - Select for the rise value. The rise value determines the automatic adjustment of the flow set point when occlusion onset is reached.
- Flow More Information Button - Displays the More Information popup which simplifies large value changes by providing slider controls. Also provides the capability to initiate a drainbag change.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending on the vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow/Vacuum Toggle: Switch between Flow mode and Vacuum mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Ultrasound Panel:

- Power Start Up/Down Buttons - When linear, set power at treadle start in position 3.
- Power End Up/Down Buttons - Set the power at full treadle.
- Power Progress Bar and Numerical Value - Shows the current power value.
- Phaco Power More Information Button - Displays the More Information dialog.
- Phaco Pulse Rate Up/Down Buttons - Set the Phaco Pulse Rate in pulses per second (pps).
- Smart Pulse - Indicator for smart pulse. Becomes visible when power is greater than 0 and pulse on time is less than 20 ms.
- Phaco Pulse Time On Up/Down Buttons - Set the Phaco Time On percentage.
- Phaco Pulse More Information Button - Displays the More Information popup.

The following Ultrasound panel controls are available only in the Advanced view:

- Power Limit Control Type Drop List - Determines whether the power limit is fixed or linear. In Fixed, the limit is constant regardless of the footswitch treadle position. In Linear, the limit varies depending on the footswitch treadle position.

Phaco Mode: PULSED SUBMODE - OZIL® PULSE

When operating in this mode, phaco power and ultrasonic oscillations turn on and off at a frequency determined by the pulse rate (pps) setting, and on a duty cycle adjustable by the operator (Time On (%)). The remaining pulse time, or percent time off, is an off-time. The sum of phaco duty cycle and torsional duty cycle cannot exceed 100%.

For example, in Figure 2-73 the entire cycle of phaco, torsional, and off-time is 100 ms duration because of the selected pulse rate of 10 pps. Duration of the phaco, therefore, is $100\text{ ms} \times 10\% = 10\text{ ms}$, and duration of the torsional is $100\text{ ms} \times 80\% = 80\text{ ms}$. The remaining 10 ms is an off period. Note that the off period follows application of torsional ultrasound, while torsional ultrasound follows application of phaco immediately.

If Phaco Power Limit and/or Torsional Amplitude Limit are set to zero, then there are no phaco nor torsional contributions to the *OZil®* pulse, and the duty cycles (Time On (%)) are not adjustable.

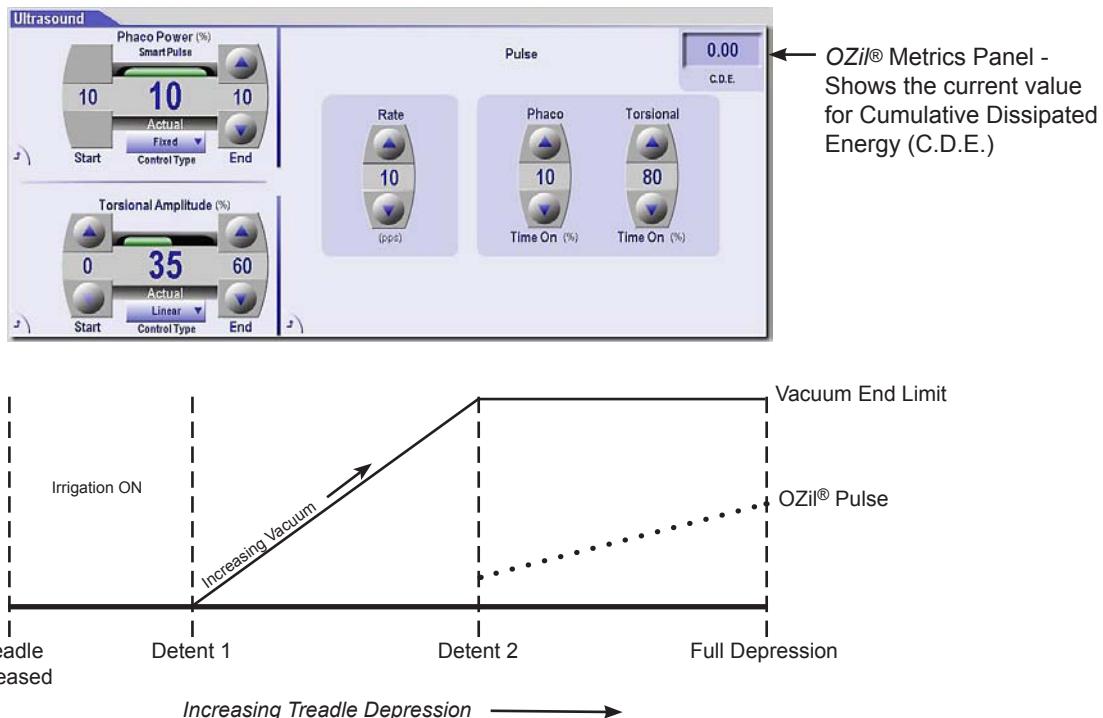


Figure 2-73 **Surgery Screen: Phaco Mode - Pulsed Submode OZil® Pulse**

Phaco Mode: CONTINUOUS SUBMODE

The Phaco Continuous submode provides continuous fixed or linear U/S power (Power %). Phaco power is controlled with the footpedal from detent two to full treadle depression. The actual percent of time U/S power is activated is reflected in the Actual window.

The controls for each panel in Continuous submode shown in Figure 2-74 have the following functions:

Vacuum Panel:

- Vacuum End Up/Down Buttons - Sets the vacuum level at full treadle.
- Vacuum More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls. Also provides the capability to initiate a drainbag change.

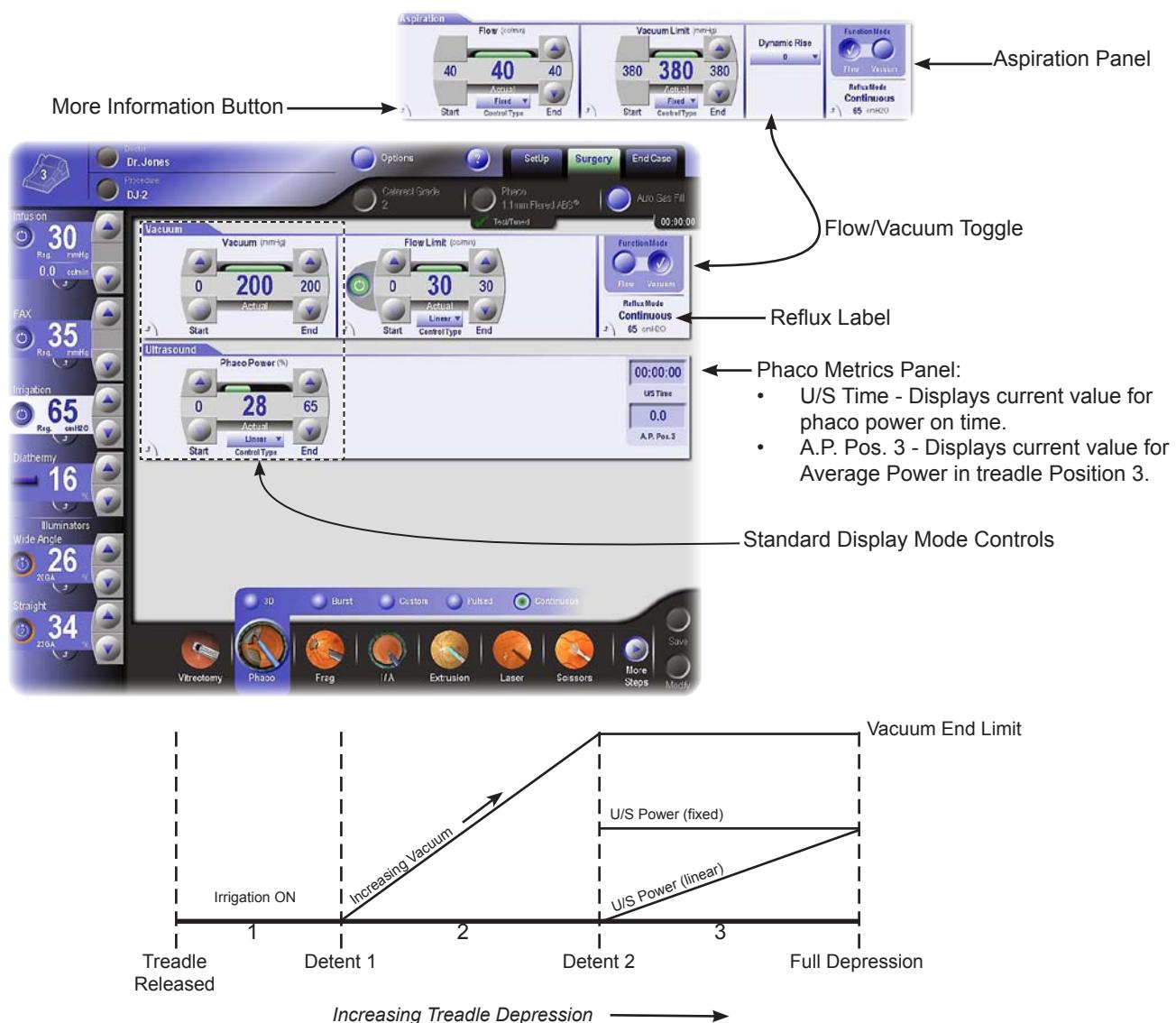


Figure 2-74 **Surgery Screen: Phaco Mode - Continuous Submode (Advanced view shown)**

The following vacuum controls are available only in the Advanced View:

- Flow Limit On/Off Button - Turns Flow Limit on or off. When the maximum rate is reached, the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the Start and End values.
- Flow Start and End Up/Down Buttons - Set the start and end limits for flow rate.
- Flow Limit Progress Bar and Numerical Value - Show the current flow level.
- Flow Limit More Information Button - Displays the More Information popup.
- Flow Limit Control Type Drop List - Determines whether the flow limit is fixed or linear. In Fixed the limit is constant regardless of the flow level. In Linear the limit varies depending on the flow level.
- Flow/Vacuum Toggle - Switches between Flow Mode and Vacuum Mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Aspiration Panel (This control is available only in the Advanced view by switching the Function Mode from Vacuum to Flow):

- Flow Start Up/Down Buttons - When linear, set the flow level at treadle start of position 2.
- Flow End Up/Down Buttons - Set the flow level at end of treadle position 2.
- Dynamic Rise Drop List - Selects the rise value. The rise value determines the automatic adjustment of the flow set point when occlusion onset is reached.
- Flow More Information Button - Displays the More Information popup which simplifies large value changes by providing slider controls. Also provides the capability to initiate a drainbag change.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending on the vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow/Vacuum Toggle: Switches between Flow mode and Vacuum mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Ultrasound Panel:

- Phaco Power Start Up/Down Buttons - When linear, set power at treadle start of position 3.
- Phaco Power End Up/Down Buttons - Set the power at full treadle.
- Phaco Power Progress Bar and Numerical Value - Shows the current power value.
- Ultrasound More Information Button - Displays the More Information popup.

The following Ultrasound panel controls are available only in the Advanced view:

- Power Limit Control Type Drop List - Determines whether the power limit is fixed or linear. In Fixed, the limit is constant regardless of the footswitch treadle position. In Linear, the limit varies depending on the footswitch treadle position.

Phaco Mode: CONTINUOUS SUBMODE - OZIL® CONTINUOUS

When the Phaco Power default setting is set to 0 (no phaco power), then only torsional ultrasonic oscillations at the preset Torsional Amplitude are delivered, for 100% of the time, to the handpiece tip. This allows the user to have continuous torsional ultrasonic oscillations if so desired. If U/S power is added, then this mode of operation provides 20% of its duty cycle for phaco power, then torsional ultrasonic oscillations for the remaining 80% when in footpedal position 3, and repeats this cycle as long as the footpedal is in position 3. This produces continuous U/S alternations between phaco power and torsional amplitude.

The user can select between fixed or linear for both Phaco Power and Torsional Amplitude from the Control Type drop down list on each control.

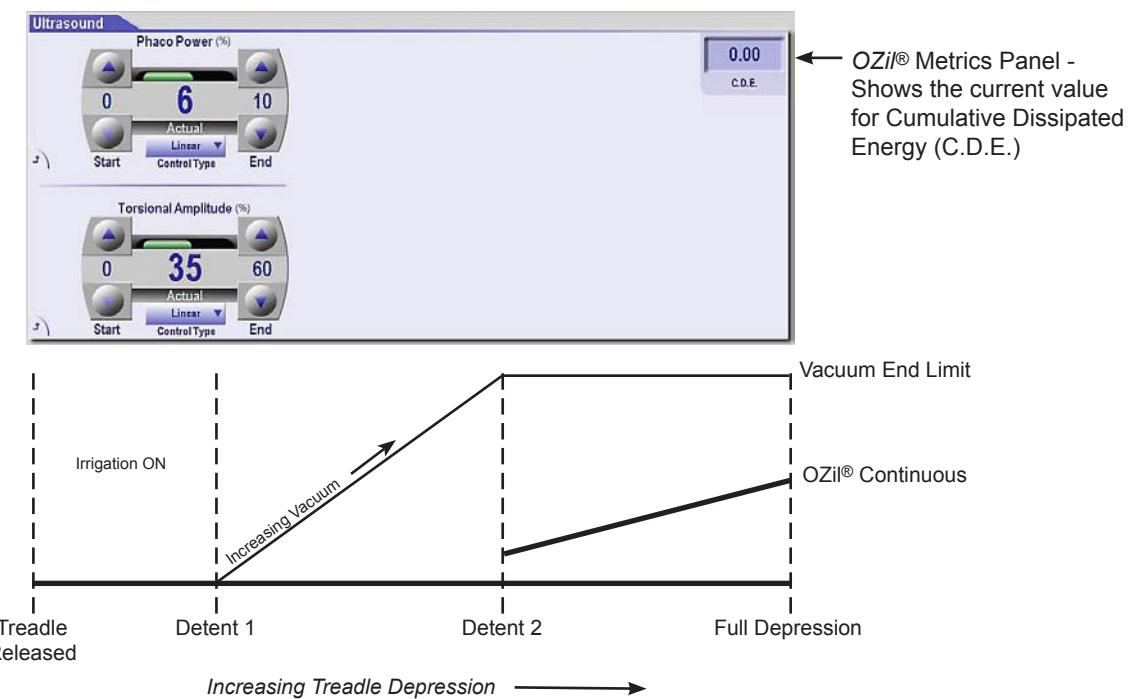


Figure 2-75 Surgery Screen: Phaco Mode - Continuous Submode - OZIL® Continuous

FRAGMENTATION MODE

Fragmentation mode is enabled when a fragmentation handpiece is connected to the system and the Fragmentation Surgery step is selected. Four submodes are available, each with its own default U/S power and vacuum limits. U/S power is enabled and disabled using the footswitch or by pressing the power setting on the touch screen (except in momentary mode). Micro and proportional reflux are available via the footswitch. U/S Pulse controls are available in all submodes.

Fragmentation Mode: 3D SUBMODE

In Fragmentation 3D submode, vacuum and U/S power delivered to the probe are simultaneously regulated by the amount of footpedal depression. The display contains adjustable values for vacuum level at treadle start and at full depression; and U/S power at treadle start and at full depression.

To prevent generating excessive flow when the footpedal is first depressed, the vacuum level is ramped up from zero to the set starting level during the first part of the pedal travel. The Ramping % is selected in the Doctor's Settings screen with an available range of 15-90%.

The 3D submode screen is shown in Figure 2-76 along with a graphic representation of the functions in each footswitch treadle position. Note that the start and end limits for both U/S Power and vacuum are adjustable therefore any combination of limits is valid. The graphic shows only one possibility.

The controls for each panel in 3D submode have the following functions:

Vacuum Panel:

- Vacuum Start Up/Down Buttons - Set the vacuum level at treadle start.
- Vacuum End Up/Down Buttons - Set the vacuum level at full treadle.
- Vacuum More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls. Also provides the capability to initiate a drainbag change.

The following vacuum controls are available only in the Advanced View:

- Flow Limit On/Off Button - Turns Flow Limit on or off. When the maximum rate is reached, the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the Start and End values.
- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for flow rate.
- Flow Limit Progress Bar and Numerical Value - Show the current flow level.
- Flow Limit More Information Button - Displays the More Information popup.
- Flow Limit Control Type Drop List - Determines whether the flow limit is fixed or linear. In Fixed the limit is constant regardless of the flow level. In Linear the limit varies depending on the flow level.
- Flow/Vacuum Toggle - Switches between Flow Mode and Vacuum Mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

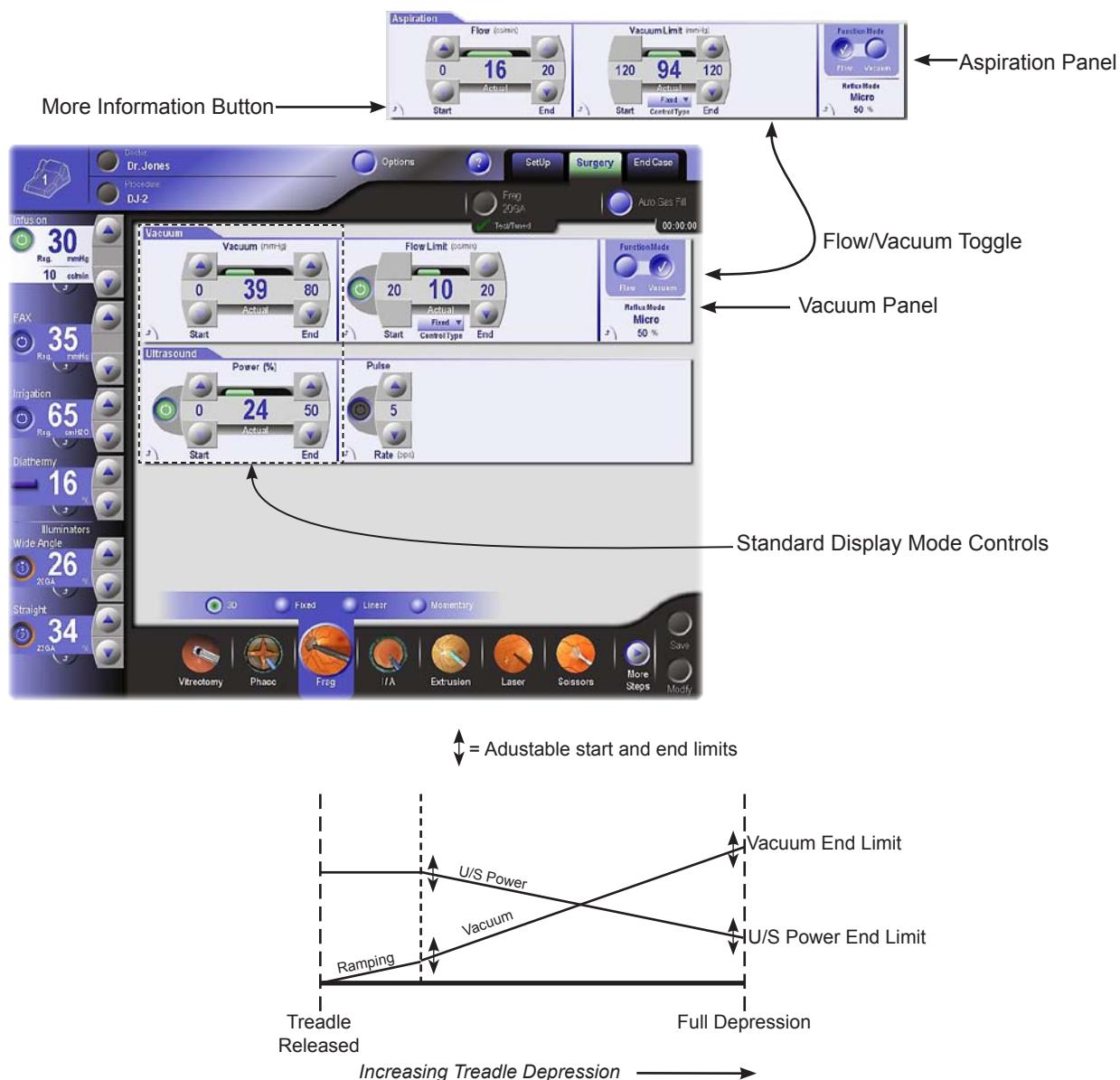


Figure 2-76 **Surgery Screen: Fragmentation Mode - 3D Submode (Advanced view shown)**

Aspiration Panel (This control is available only in the Advanced view by switching the Function Mode from Vacuum to Flow):

- Flow Start Up/Down Buttons - Set the flow level at treadle start.
- Flow End Up/Down Buttons - Set the flow level at full treadle.
- Flow More Information Button - Displays the More Information popup which simplifies large value changes by providing slider controls. Also provides the capability to initiate a drainbag change.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending upon treadle depression.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow/Vacuum Toggle: Switches between Flow mode and Vacuum mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Ultrasound Panel:

- Phaco Power Start Up/Down Buttons - Set the power level at treadle start.
- Phaco Power End Up/Down Buttons - Set the power at full treadle.
- Phaco Power Progress Bar and Numerical Value - Show the current power value.
- Ultrasound More Information Button - Displays the More Information popup.
- Pulse Rate On/Off Button - Turns the Pulse Rate on or off.
- Pulse Rate Up/Down Buttons - Set the pulse rate.
- Pulse More Information Button - Displays the More Information popup.

Fragmentation Mode: FIXED SUBMODE

In Fixed submode shown in Figure 2-77, the vacuum level is controlled linearly from 0 to the set value whereas the ultrasound power level is fixed. The controls for each panel in Fixed submode have the following functions:

Vacuum Panel:

- Vacuum End Up/Down Buttons - Set the vacuum level at the end of treadle position 1.
- Vacuum Progress Bar and Numerical Value - Display the current vacuum level.
- Vacuum More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls. Also provides panel specific configuration capabilities such as Drainbag Change.

The following Vacuum controls are available only in the Advanced view:

- Flow Limit On/Off Button - Turns Flow Limit on or off. When the maximum rate is reached, the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the End value.
- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for flow rate.
- Flow Limit Control Type Drop List - Determines whether the flow limit is fixed or linear. In Fixed, the limit is constant regardless of the flow level. In Linear, the limit varies depending on the flow level.
- Flow Limit Progress Bar and Numerical Value - Displays the current flow rate.
- Flow/Vacuum Toggle - Switches between Flow Mode and Vacuum Mode.
- Flow Limit More Information Button - Displays the More Information popup.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Aspiration Panel (This panel is available only in the Advanced View when the Flow button is selected.)

- Flow End Up/Down Buttons - Set the flow level at full treadle.
- Flow Progress Bar and Numerical Value - Display the current flow level.
- Aspiration More Information Button - Displays the More Information popup.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.

- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending on the vacuum level.
- Vacuum Limit Progress Bar and Numerical Value - Display the current vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow / Vacuum Toggle - Switches between Flow mode and Vacuum mode.

Ultrasound Panel:

- Power On/Off Button - Turns ultrasound power on or off.
- Power End Up/Down Buttons - Set the power at full treadle. The Start value tracks with the End value.
- Power Progress Bar and Numerical Value - Display the current power value.
- Ultrasound More Information Button - Displays the More Information popup.
- Pulse Rate On/Off Button - Turns the Pulse Rate on or off.
- Pulse Rate Up/Down Buttons - Set the pulse rate.
- Pulse More Information Button - Displays the More Information popup.

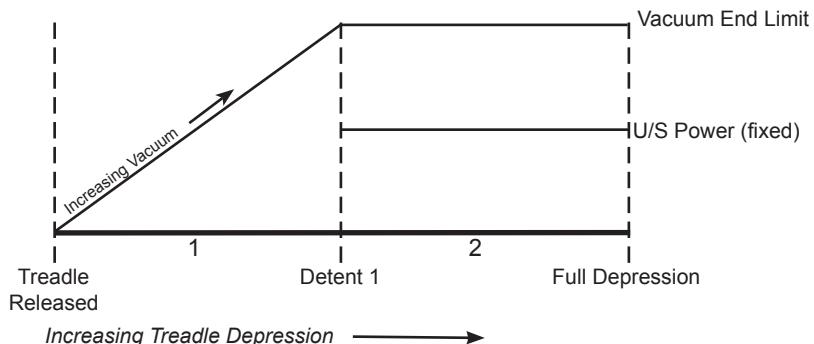
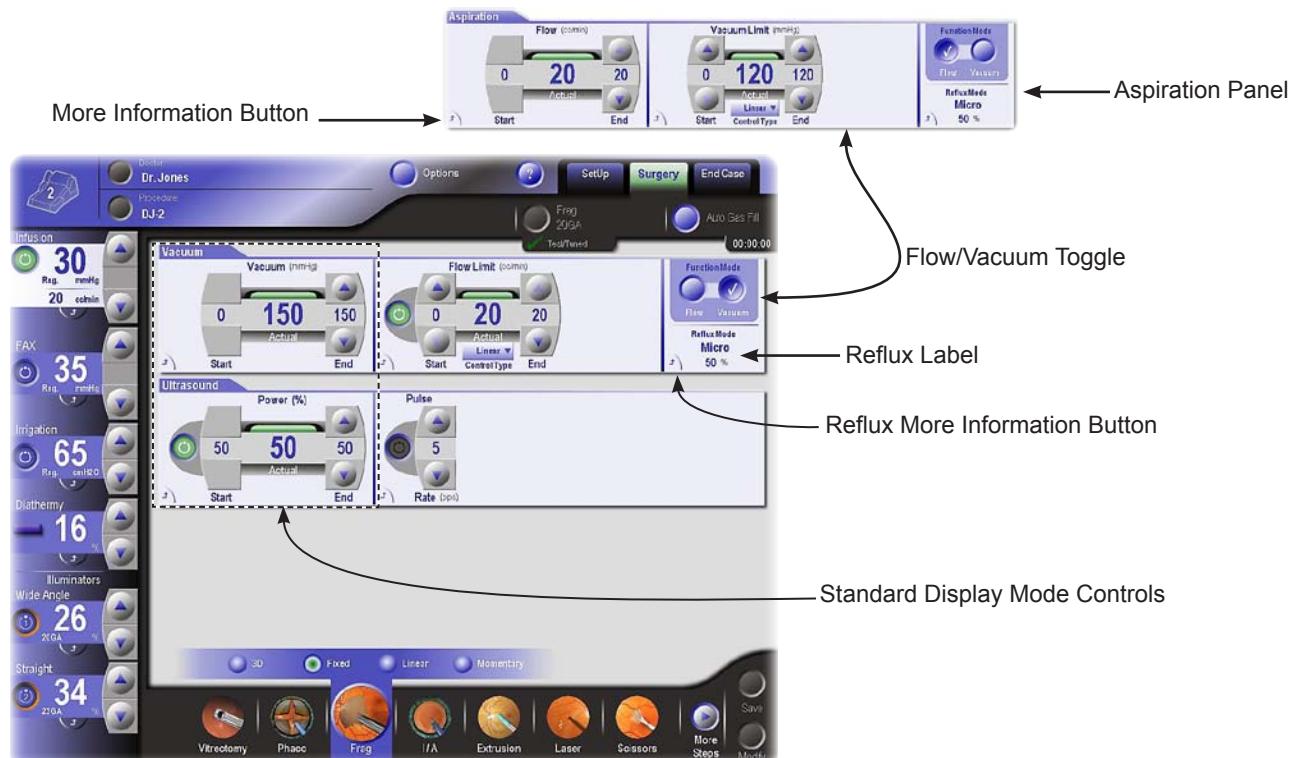


Figure 2-77 Surgery Screen: Fragmentation Mode - Fixed Submode (Advanced view shown)

Fragmentation Mode: LINEAR SUBMODE

Linear submode is very similar to the Fixed submode with the exception that the treadle start values for both vacuum and ultrasound power are fixed at 0.

The controls for each panel in Linear submode shown in Figure 2-78 have the following functions:

Vacuum Panel:

- Vacuum End Up/Down Buttons - Set the vacuum level at the end of treadle position 1.
- Vacuum Progress Bar and Numerical Value - Display the current vacuum level.
- Vacuum More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls. Also provides panel specific configuration capabilities such as Drainbag Change.

The following Vacuum panel controls are available only in the Advanced view:

- Flow Limit On/Off Button - Turns Flow Limit on or off. When the maximum rate is reached, the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the End value.

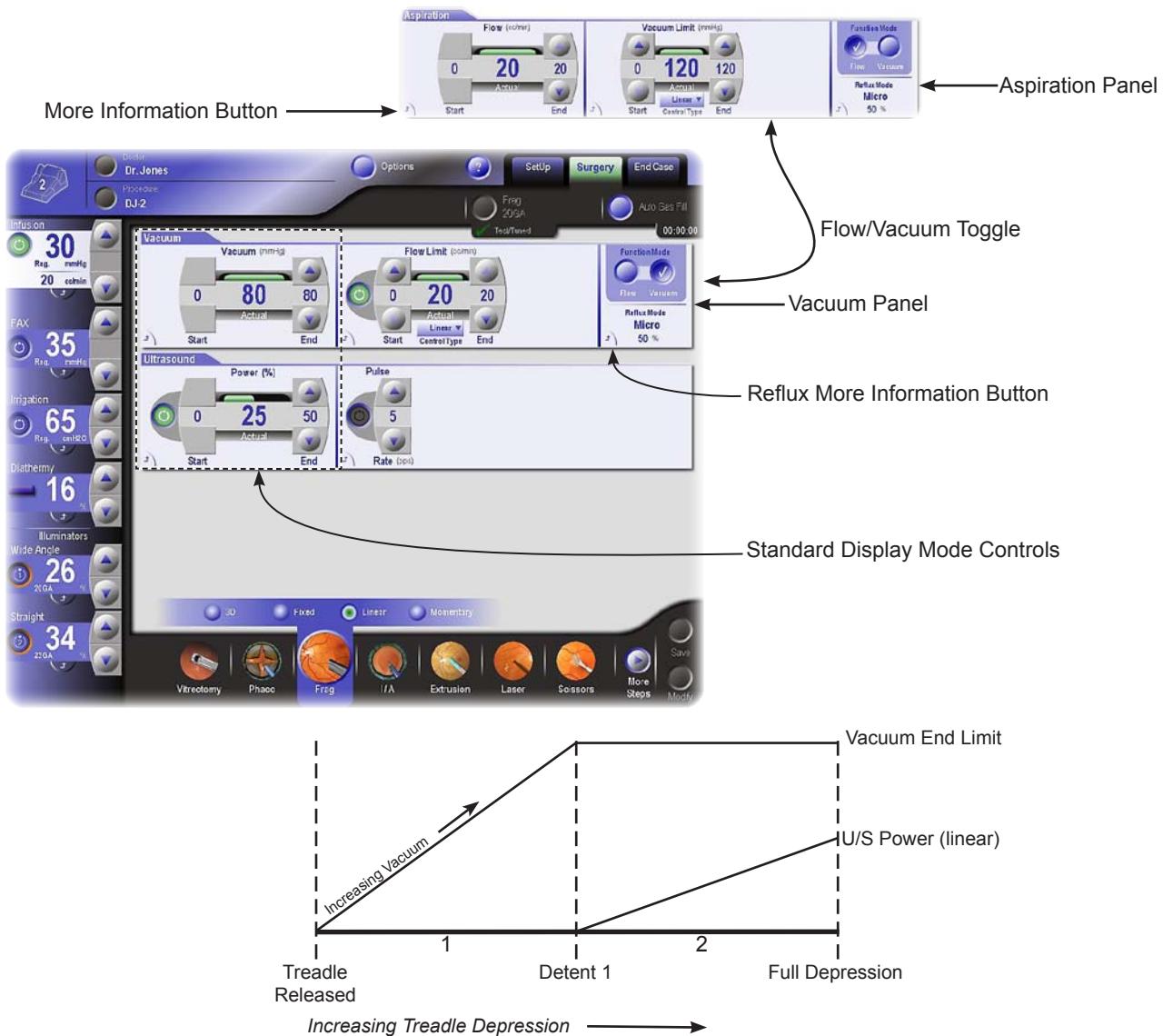


Figure 2-78 Surgery Screen: Fragmentation Mode - Linear Submode (Advanced view shown)

- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for flow rate.
- Flow Limit Progress Bar and Numerical Value - Display the current flow rate.
- Flow / Vacuum Toggle - Switches between Flow mode and Vacuum mode.
- Flow Limit More Information Button - Displays the More Information popup.
- Flow Limit Control Type Drop List - Determines whether the flow limit is fixed or linear. In Fixed, the limit is constant regardless of the flow level. In Linear, the limit varies depending on the flow level.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Aspiration Panel (This panel is available only in the Advanced View when the Flow button is selected.)

- Flow End Up/Down Buttons - Set the flow level at the end of treadle position 1.
- Flow Progress Bar and Numerical Value - Display the current flow level.
- Aspiration More Information Button - Displays the More Information popup.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Progress Bar and Numerical Value - Display the current vacuum level.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending on the vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow / Vacuum Toggle - Switches between Flow mode and Vacuum mode.

Ultrasound Panel:

Same as Fixed submode except that the start value is always zero then the U/S power is increased linearly as the treadle is depressed.

- Power On/Off Button - Turns ultrasound Power on or off.
- Power End Up/Down Buttons - Set the Power at full treadle.
- Power Progress Bar and Numerical Value - Display the current power value.
- Ultrasound More Information Button - Displays the More Information popup.
- Pulse Rate On/Off Button - Turns the Pulse Rate on or off.
- Pulse Rate Up/Down Buttons - Set the pulse rate.
- Pulse More Information Button - Displays the More Information popup.

Fragmentation Mode: MOMENTARY SUBMODE

Momentary submode is similar to the Fixed submode with the exception that fixed ultrasound is only active when the assigned switch on the footswitch button is pressed. See Doctor Settings/Footswitch for switch assignment.

Vacuum Panel:

- Vacuum End Up/Down Buttons - Set the vacuum level at the end of treadle position 1.
- Vacuum Progress Bar and Numerical Value - Display the current vacuum level.
- Vacuum More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls. Also provides panel specific configuration capabilities such as Drainbag Change.

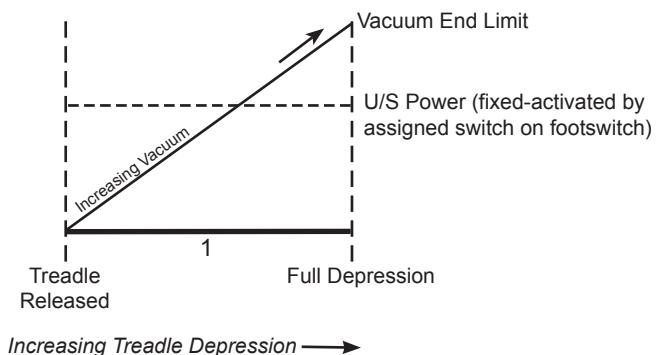
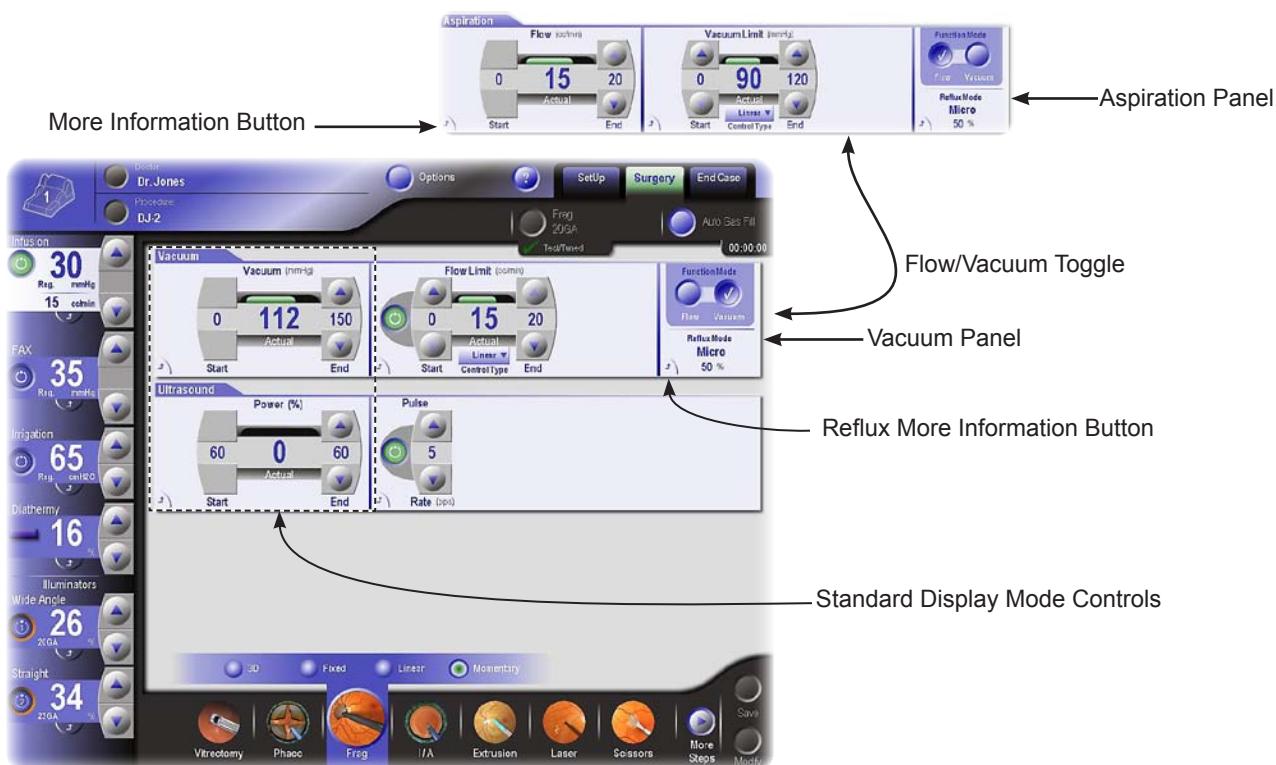


Figure 2-79 Surgery Screen: Fragmentation Mode - Momentary Submode (Advanced view shown)

The following Vacuum controls are available only in the Advanced view:

- Flow Limit On/Off Button - Turns flow limit on or off. When the maximum rate is reached, the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the End value.
- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for flow rate.
- Flow Limit Progress Bar and Numerical Value - Display the current flow rate.
- Flow Limit Control Type Drop List - Determines whether the flow limit is fixed or linear. In Fixed, the limit is constant regardless of the flow level. In Linear, the limit varies depending on the flow level.
- Flow / Vacuum Toggle - Switches between Flow mode and Vacuum mode.
- Flow Limit More Information Button - Displays the More Information popup.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Aspiration Panel (This panel is available only in the Advanced View when the Flow button is selected.)

- Flow End Up/Down Buttons - Set the flow level at full treadle.
- Flow Progress Bar and Numerical Value - Display the current flow level.
- Aspiration More Information Button - Displays the More Information popup.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Progress Bar and Numerical Value - Display the current vacuum level.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending on the vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow / Vacuum Toggle - Switches between Flow mode and Vacuum mode.

Ultrasound Panel:

Same as Fixed submode except that there is no On/Off button to turn U/S power Off.

- Power End Up/Down Buttons - Set the power at full treadle. The Start value tracks with the End value.
- Power Progress Bar and Numerical Value - Displays the current power value.
- Ultrasound More Information Button - Displays the More Information popup.
- Pulse Rate On/Off Button - Turns the Pulse Rate on or off.
- Pulse Rate Up/Down Buttons - Sets the pulse rate.
- Pulse More Information Button - Displays the More Information popup.

IRRIGATION/ASPIRATION (I/A) MODE

In I/A mode, the Surgery screen contains panels for controlling an IA handpiece. The vacuum pressure is always controlled linearly and vacuum cannot be turned off. When the system detects an occlusion in Flow mode, the word "Occlusion" is displayed on the extraction panel under the primary limit control's label and an alarm sounds.

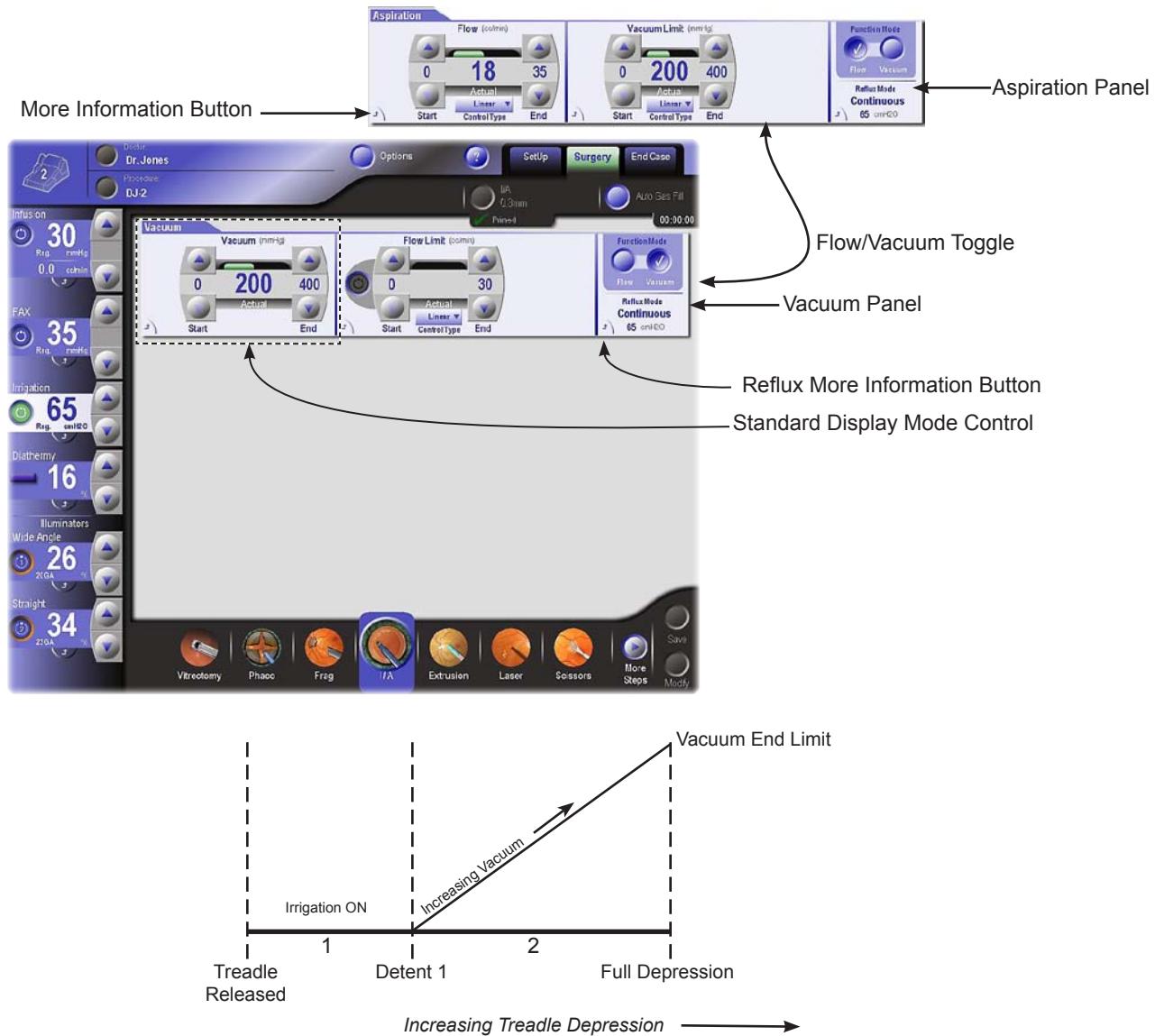


Figure 2-80 Surgery Screen: Irrigation/Aspiration Mode (Advanced view shown)

In "Standard" display mode, only the Vacuum mode controls are available. The controls for each panel in I/A mode have the following functions:

Vacuum Panel:

- Vacuum End Up/Down Buttons - Set the vacuum level at full treadle.
- Vacuum Progress Bar and Numerical Value - Display the current vacuum level
- Vacuum More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls. Also provides panel specific configuration capabilities such as Drainbag Change.

The following Vacuum panel controls are available only in the Advanced view:

- Flow Limit On/Off Button - Turns Flow Limit on or off. When the maximum rate is reached, the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the Start and End values.
- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for flow rate.
- Flow Limit Progress Bar and Numerical Value - Display the current flow rate.
- Flow / Vacuum Toggle - Switches between Flow mode and Vacuum Mode.
- Flow Limit More Information Button - Displays the More Information popup.
- Flow Limit Control Drop Down List - Determines whether the flow limit is fixed or linear. In Fixed, the limit is constant regardless of the flow level. In Linear, the limit varies depending on the flow level.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Aspiration Panel (in Advanced View only when Flow mode is selected):

- Flow Start and End Up/Down Buttons - Set the flow level at start and full treadle.
- Flow Progress Bar and Numerical Value - Display the current flow level.
- Aspiration More Information Button - Displays the More Information popup.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Progress Bar and Numerical Value - Display the current vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow / Vacuum Toggle - Switches between Flow mode and Vacuum mode.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending on the vacuum level.

EXTRUSION MODE

In Extrusion mode the Surgery screen contains the Vacuum panel necessary for controlling an extrusion handpiece. The vacuum pressure is always controlled linearly and vacuum cannot be turned off.

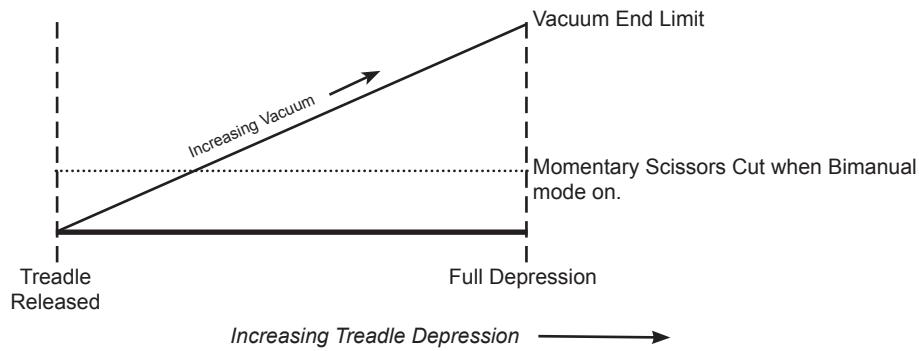
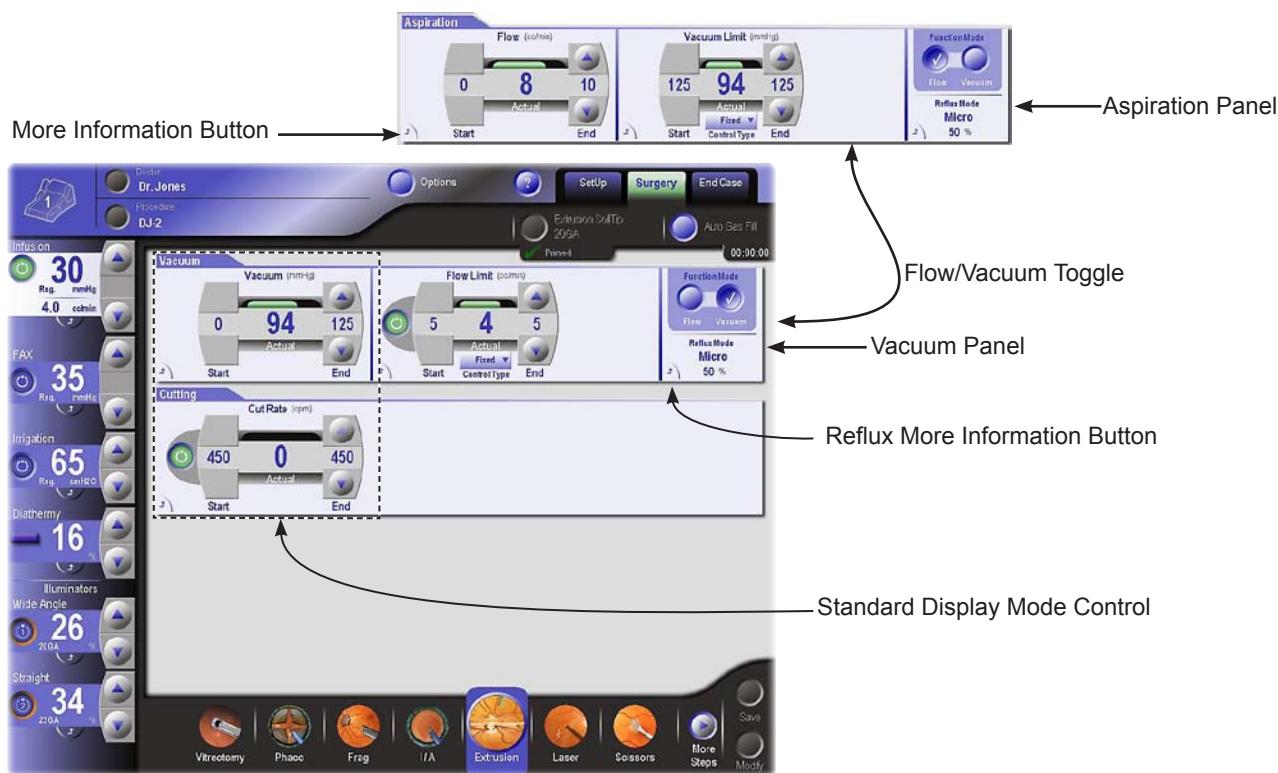


Figure 2-81 **Surgery Screen: Extrusion Mode (Advanced view shown)**

In “Standard” display mode, only the Vacuum mode controls are available. The controls for each panel in Extrusion mode have the following functions:

Vacuum Panel:

- Vacuum End Up/Down Buttons - Set the vacuum level at full treadle. The Start value is always zero.
- Vacuum Progress Bar and Numerical Value - Display the current vacuum level.
- Vacuum More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls. Also provides panel specific configuration capabilities such as Drainbag Change.

The following Vacuum panel controls are available only in the Advanced view:

- Flow Limit On/Off Button - Turns Flow Limit on or off. When the maximum rate is reached, the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the End value.
- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for flow rate.
- Flow Limit Progress Bar and Numerical Value - Display the current flow rate.
- Flow / Vacuum Toggle - Switches between Flow mode and Vacuum mode
- Flow Limit More Information Button - Displays the More Information popup.
- Flow Limit Control Type Drop Down List - Determines whether the flow limit is fixed or linear. In Fixed, the limit is constant regardless of the flow level. In Linear, the limit varies depending on the flow level.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Aspiration Panel (in Advanced View only when Flow mode is selected):

- Flow End Up/Down Buttons - Set the flow level at full treadle.
- Flow Progress Bar and Numerical Value - Display the current flow level.
- Flow More Information Button - Displays the More Information popup.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Progress Bar and Numerical Value - Display the current vacuum level.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending on the vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow / Vacuum Toggle - Switches between Flow mode and Vacuum mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Cutting Panel:

- Cut Rate End Up/Down Buttons - Set the cut rate.
- Cut Rate Progress Bar and Numerical Value - Display the current cut rate.
- Cutting More Information Button - Displays the More Information popup.

LASER MODE

In Laser Mode the Surgery screen contains panels for controlling a laser probe as well as an aspirating handpiece (which could be the laser probe). The laser function has three modes that enable the different operational states of the system.

Laser Modes:

- Standby – Settings can be adjusted in this mode, but the system cannot deliver treatment laser energy.
- Ready Mode - This mode is initiated when the Standby/Ready button or the right side switch (if enabled) on laser footswitch is pushed while the system is in Standby mode. After the button is pushed, the laser transitions into Ready mode and the background color of the laser panel changes to light green. The system is now prepared to deliver treatment laser energy.
- Firing Mode - Pressing the footswitch in Ready mode causes the system to deliver laser treatment energy. The message “LASER FIRING” is displayed during this time.

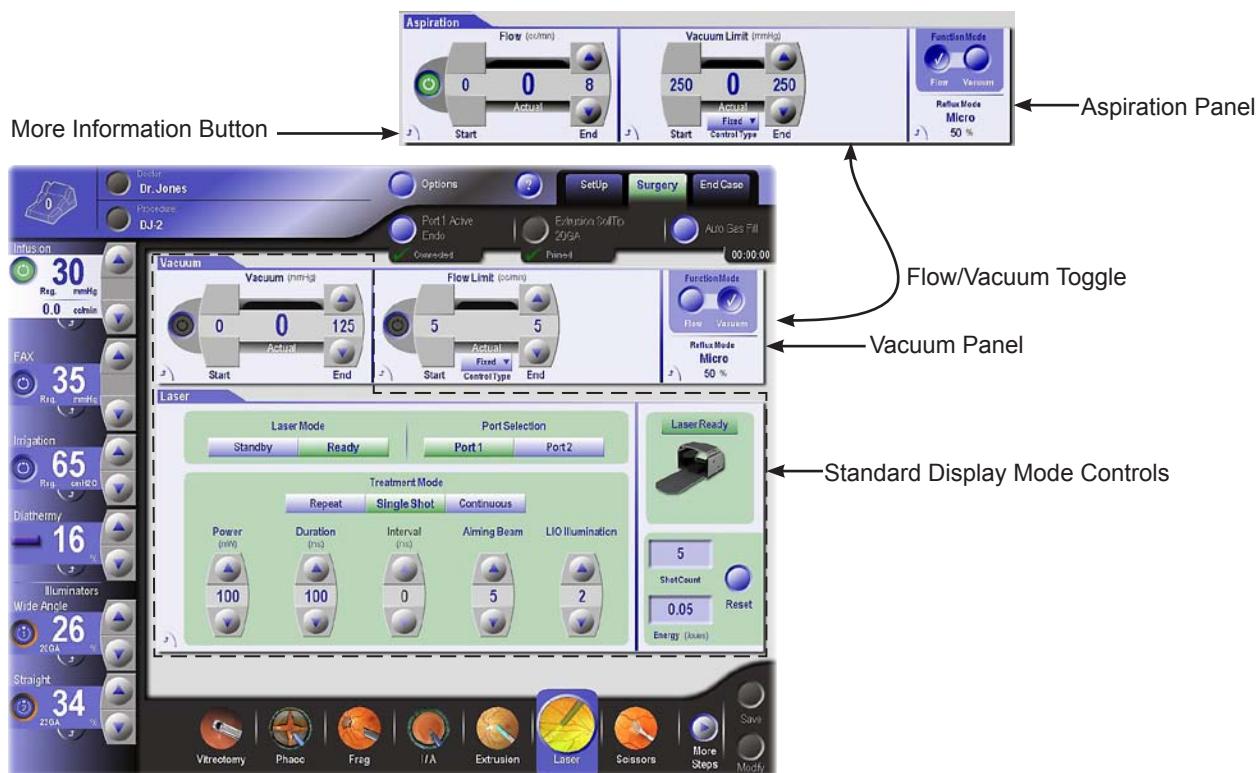


Figure 2-82 Surgery Screen: Laser Mode

The system has three treatment modes that determine how the treatment laser shots are delivered.

Treatment Modes:

- Repeat – Generates laser shots continuously when the laser footswitch treadle is depressed.
- Single Shot – When the laser footswitch treadle is pressed down, the laser fires a single shot. The Interval buttons are inactive in this mode.
- Continuous – The laser keeps firing as long as the laser footswitch treadle is depressed. The Duration and Interval buttons are inactive in this mode.

Laser Panel:

- Laser Mode - Selects laser Standby or Ready mode.
- Port Selection - Selects the port used for treatment.
- Treatment Mode - Selects the Treatment mode: Repeat, Single Shot, or Continuous.
- Power Up/Down Buttons - Adjust the treatment laser power to the values shown in the table below:

532 Green Laser Power Values (in milliwatts)

| 30 | 40 | 50 | 60 | 70 | 80 | 90 | 100 | 110 | 120 | 130 | 140 |
|------|------|------|------|------|------|------|------|-----|------|------|------|
| 150 | 160 | 170 | 180 | 190 | 200 | 220 | 240 | 250 | 260 | 280 | 300 |
| 320 | 340 | 350 | 360 | 380 | 400 | 420 | 440 | 450 | 460 | 480 | 500 |
| 550 | 600 | 650 | 700 | 750 | 800 | 850 | 900 | 950 | 1000 | 1100 | 1200 |
| 1300 | 1400 | 1500 | 1600 | 1700 | 1800 | 1900 | 2000 | | | | |

NOTE: The Constellation® Laser determines the 532 green laser maximum available power and limits the user setting to that maximum value if less than 2 W. The maximum selectable power may be less than 2 W (2000 mW) because of the degradation of the laser engine over time.

- Duration Up/Down Buttons - The Duration buttons adjust the exposure time to the following values in milliseconds: 10, 20, 50, 100, 150, 200, 250, 300, 400, 500, 700, 1000, 1500, and 2000 ms. This setting is only available in Repeat or Single Shot modes.

NOTE: In Continuous mode, depending on the thermal load of the system, the system may shut down prior to the footswitch being released, with an indication on the display. It is not recommended to use exposure times longer than 2 seconds in Continuous mode.

- Interval Up/Down Buttons - The Interval is the time between treatment shots when the treatment mode is set for Repeat mode. The Interval Time buttons adjust the interval time to the following values:
 - 30 ms to 100 ms in 10 ms steps
 - 100 ms to 300 ms in 50 ms steps
 - 300 ms up to 1 second duration in 100 ms steps
- Aiming Beam Up/Down Buttons - Adjustment of the current relative intensity (0-10) of the aiming beam.
- LIO Illumination Up/Down Buttons - Adjustment of the LIO illumination intensity (0-10).
- Shot Count Label - Displays the current shot count. Pressing the Reset button resets the shot count to zero.
- Energy Label - Displays the total energy. Pressing the Reset button resets the Total Energy display to zero.
- Laser More Information Button - Displays the More Information popup which simplifies large value changes by providing slider controls.

NOTES:

In tethered mode, all front panel controls on the tethered laser console except for the emergency switch, the key switch, and the two port buttons are disabled.

The laser is controlled/fired by the laser footswitch and the vacuum is controlled by the Constellation® footswitch.

In “Standard” display mode, only the Vacuum mode controls are available. The controls for each panel in Laser mode have the following functions:

Vacuum Panel:

- Vacuum On/Off Button - Turns vacuum off or on.
- Vacuum End Up/Down Buttons - Sets the vacuum level at full treadle. The Start value is always zero.
- Vacuum Progress Bar and Numerical Value - Displays the current vacuum level.
- Vacuum More Information Button - Displays the More Information popup, which simplifies large value changes by providing slider controls. Also provides panel specific configuration capabilities such as Drainbag Change.

The following Vacuum panel controls are available only in the Advanced view:

- Flow Limit On/Off Button - Turns Flow Limit on or off. When the maximum rate is reached, the vacuum level can no longer be increased. If the Flow Limit is turned off, the vacuum level is limited only by the End value.
- Flow Limit Start and End Up/Down Buttons - Set the start and end limits for flow rate.
- Flow Limit Progress Bar and Numerical Value - Display the current flow rate.
- Flow Limit More Information Button - Displays the More Information popup.
- Flow Limit Control Drop Down List - Determines whether the flow limit is fixed or linear. In Fixed, the limit is constant regardless of the flow level. In Linear, the limit varies depending on the footswitch treadle position.
- Flow / Vacuum Toggle - Switches between Flow mode and Vacuum mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

Aspiration Panel (in Advanced View only when Flow mode is selected):

- Flow On/Off Button - Turns flow off or on.
- Flow End Up/Down Buttons - Set the flow level at full treadle.
- Flow Progress Bar and Numerical Value - Display the current flow level.
- Flow More Information Button - Displays the More Information popup.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Limit Progress Bar and Numerical Value - Display the current vacuum level.
- Vacuum Limit Control Type Drop List - Determines whether the vacuum limit is fixed or linear. In Fixed the limit is constant regardless of the vacuum level. In Linear the limit varies depending on the vacuum level.
- Vacuum Limit More Information Button - Displays the More Information popup.
- Flow / Vacuum Toggle - Switches between Flow mode and Vacuum mode.
- Reflux Label - Read Only display of the current reflux configuration together with its current value.
- Reflux More Information Button - Displays the Reflux More Information popup.

FORCEPS MODE

The Forceps Pressure Panel controls the pressure for opening and closing pneumatic forceps. Figure 2-83 shows the Forceps surgery screen. The controls for each panel in Forceps mode have the following functions:

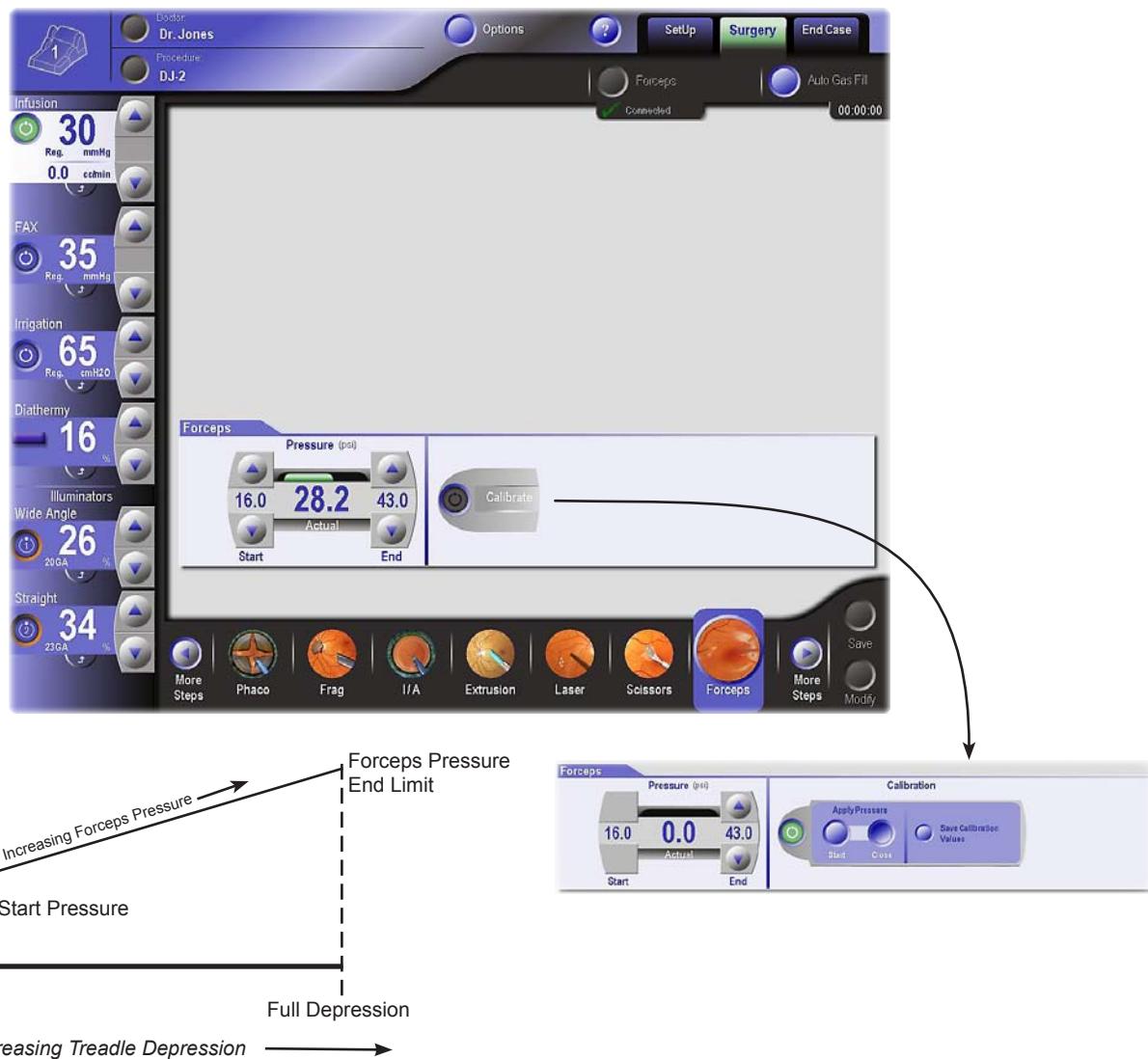


Figure 2-83 **Surgery Screen: Forceps Mode**

Forceps Panel:

- Pressure Start Up/Down Buttons - Set the pressure at treadle start.
- Pressure End Up/Down Buttons - Set the pressure at full treadle.
- Pressure Progress Bar and Numerical Value - Display the current pressure value.
- Forceps More Information Button - Displays the More Information popup.
- Calibrate On/Off Button - Enters Calibration mode allowing the user select and set the pressure at Start and Close.
 - When Start is selected, the Start pressure is applied to the port and the Start Up/Down buttons are active on the Pressure control to allow adjustment of the Start pressure.
 - When Close is selected, the Close pressure is applied to the port and the Close Up/Down buttons are active on the Pressure control to allow adjustment of the Close pressure.
 - Pressing the "Save Calibration Values" button saves these values.

SCISSORS MODE

The Scissors mode provides cutting capability using pneumatically powered scissors controlled by the footswitch. The pneumatically powered scissors use a microscissors snapped onto the *Alcon®/Grieshaber®* pneumatic handpiece, which is connected via tubing to a front panel pneumatic port. Two submodes are available: MultiCut and Prop (Proportional). In Scissors mode the surgery screen contains panels for controlling scissors and bimanual forceps.

WARNING!

Ensure proper scissors tip attachment to pneumatic handpiece. Prior to use in eye, depress footpedal\button to ensure proper tip function.

Scissors Mode: MULTICUT SUBMODE

In the MultiCut submode, pressing the footpedal activates the scissors at a cut rate proportional to the footpedal position up to the preset End limit, set by pressing the up/down buttons next to the End limit readout. Single cuts are possible by adjusting the cut rate to 1 cpm and momentarily pressing the footpedal.

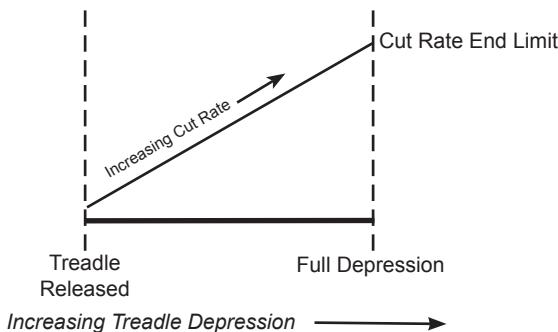
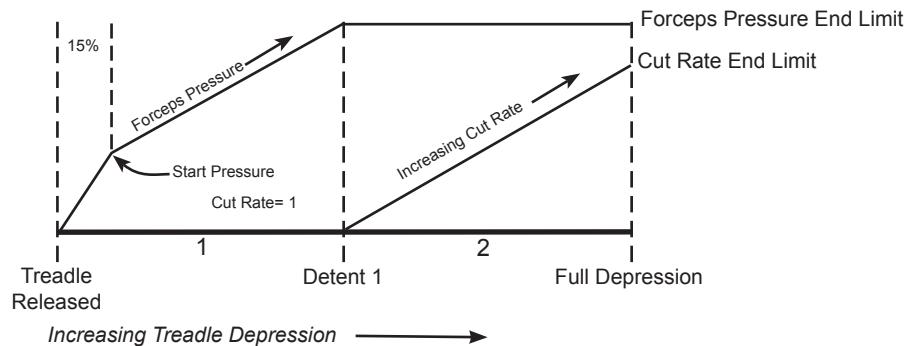
The controls for each panel in Scissors MultiCut submode have the following functions:

Cutting Panel:

- Cut Rate End Up/Down Buttons - Set the cut rate end limit.
- Cut Rate Progress Bar and Numerical Value - Display the current cut rate.
- Cutting More Information Button - Displays the More Information popup.

Forceps Panel:

- Bimanual On/Off Button - Turning Bimanual mode on allows the control of the pneumatic forceps while the system is in Scissors mode. All controls function the same as when the system is in Forceps mode (see Forceps mode for a description).

**BIMANUAL MODE****Figure 2-84** Surgery Screen: Scissors Mode - MultiCut

Scissors Mode: PROP SUBMODE

The Proportional submode provides proportional control of the opening and closing of the scissor blades, dependent upon the amount of footpedal depression. The amount of scissors closure is indicated in the Pressure panel. When the footpedal is fully depressed, the Close Limit is reached, and scissors should be fully closed. Pressing the On/Off button in the Calibration panel displays the Calibration panel that allows the user to adjust the scissors Start and Close Pressures.

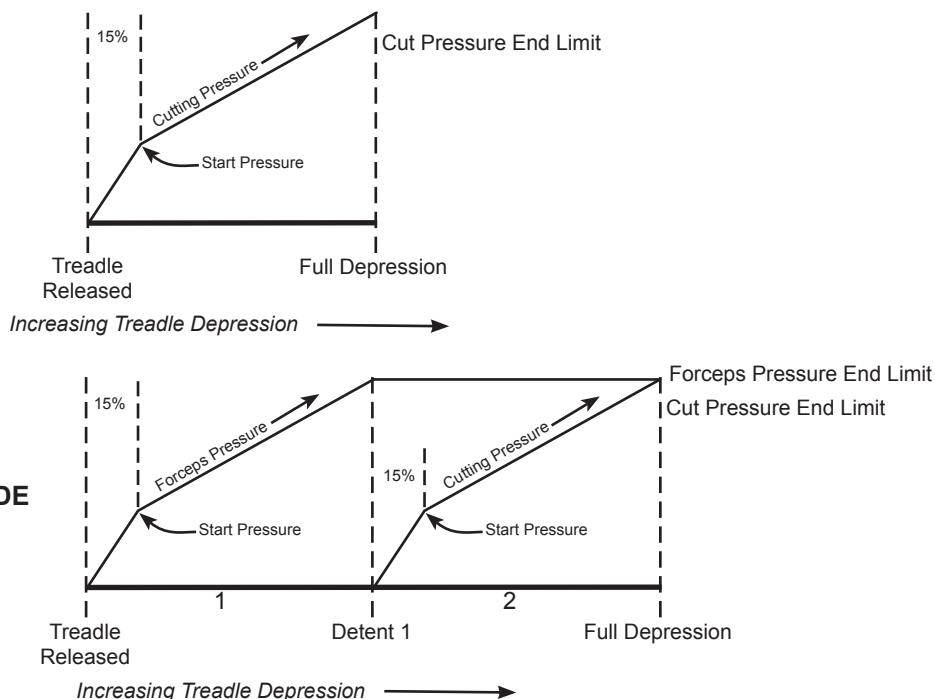


Figure 2-85 Surgery Screen: Scissors Mode - Proportional

The controls for each panel in Scissors Proportional submode have the following functions:

Cutting Panel:

- Pressure Start Up/Down Buttons - Set the pressure at treadle start.
- Pressure End Up/Down Buttons - Set the pressure at full treadle.
- Pressure Progress Bar and Numerical Value - Display the current cut rate.
- Cutting More Information Button - Displays the More Information popup.
- Calibrate On/Off Button - Enters Calibration Mode allowing the user to select and set the pressure at Start and Close.
 - When Start is selected, the Start pressure is applied to the port and the Start Up/Down buttons are active on the Pressure control to allow adjustment of the Start pressure.
 - When Close is selected, the Close pressure is applied to the port and the Close Up/Down buttons are active on the Pressure control to allow adjustment of the Close pressure.
 - Pressing the Save Calibration Values button saves these values.

Forceps Panel:

- Bimanual On/Off Button - Turning Bimanual mode on allows the control of the pneumatic forceps while the system is in Scissors mode. All controls function the same as when the system is in Forceps mode (see Forceps mode for a description).

VISCOS FLUID CONTROL (VFC) MODE

The VFC (Viscous Fluid Control) mode provides pressure at the front panel VFC connector for fluid injection (i.e., silicone oil), or vacuum for extraction, through the VFC tubing set to a syringe. Using vacuum, the VFC mode also provides a means of extruding fluid through the VFC syringe.

CAUTION

Always use Alcon-supplied Viscous Fluid Control Kits and follow all Directions for Use. Do not use VFC without the plunger/stopper supplied with the kit. Do not aspirate fluids directly into the console; this will cause damage to the console, increase risk of electrical shock, and void all warranties.

Viscous Fluid Control (VFC) Mode: EXTRACT SUBMODE

Vacuum for fluid extraction is provided to the syringe proportional to footpedal depression. Max Limit vacuum is reached at full depression. The controls on the Extraction panel have the following functions:

- Vacuum End Up/Down Buttons - Set the vacuum level at full treadle. Start value is always zero.
- Vacuum Progress Bar and Numerical Value - Display the current vacuum level.
- Extraction More Information Button - Displays the More Information popup that simplifies large value changes by providing slider controls.

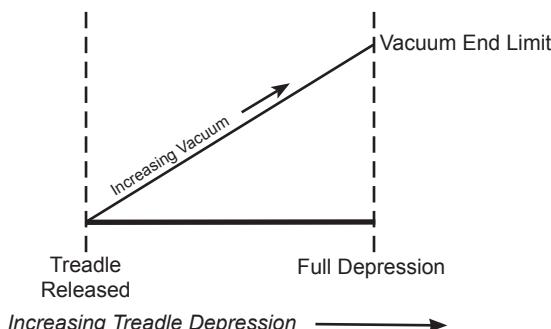


Figure 2-86 Surgery Screen: VFC Mode - Extract Submode

Viscous Fluid Control (VFC) Mode: INJECT SUBMODE

In this submode injection pressure to the syringe is provided proportional to the footpedal position up to the Max Limit setting. Vacuum is available in Bimanual mode by pressing the Bimanual On/Off button.

WARNINGS!

- Double check the cannula connected to the syringe for a tight connection. It must not be allowed to come loose.
- Adjust the Max Limit air pressure in accordance with the viscosity of fluids to be injected.

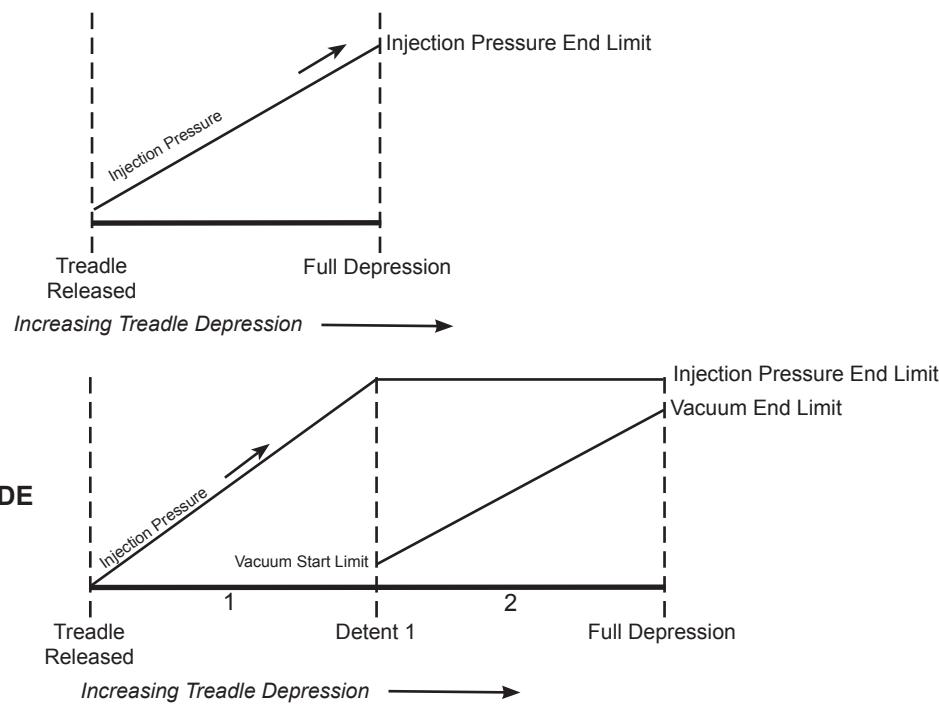


Figure 2-87 Surgery Screen: VFC Mode - Injection Submode

Vacuum Panel controls:

- Bimanual-Vacuum On/Off Button - Turns Vacuum on or off. When Bimanual mode is on, the control displayed is a dual value control.
- Vacuum Limit Start and End Up/Down Buttons - Set the start and end limits for vacuum.
- Vacuum Progress Bar and Numerical Value - Display the current vacuum level.
- Vacuum More Information Button - Displays the More Information popup which simplifies large value changes by providing slider controls.

The following Vacuum panel controls are available only in the Advanced view:

- Reflux Label - Read only display of the current Reflux configuration and its current value.
- Reflux More Information Button - Displays the Reflux More Information popup allowing the selection of Proportional (1-120 mmHg) or Micro (10-100%) Reflux.

Injection Panel controls:

- Pressure End Up/Down Buttons - Set the pressure value at full treadle. Start value is always zero.
- Pressure Progress Bar and Numerical Value - Display the current vacuum level.
- Injection More Information Button - Displays the More Information popup which simplifies large value changes by providing slider controls.

END CASE

The End Case screen, selected by pressing the End Case tab, displays case related metrics as shown in Figure 2-88. It consists of a Summary panel area and a tabbed interface area for displaying the various metrics associated with the case. The screen also provides various controls for renaming the case, printing the End Case and Laser forms, and customizing the form's content and layout via the Setup Form popup.



Figure 2-88 End Case Screen: Anterior Tab

Viewing of the various metrics associated with the case is accomplished by selecting the associated tabs - Anterior, Posterior, Laser, or Consumables. Pressing the Rename button above the tabs displays a keyboard which enables the user to rename the case from the default name (date of surgery).

The Print and Print Laser Form buttons are used to obtain a print-out of the End Case Form and Laser Form respectively. The Laser Form is comprised of the End Case Form's first header and the Laser metrics table only. Modification of the End Case Form's layout and content is accomplished using the Setup Form button, which when pressed, displays the End Case Form Setup popup.

NOTE: If the current procedure has been modified, the user will be prompted to "Save" or "Save to a New Procedure."

End Case Summary Panel

The Summary panel area lists those procedure steps that were used during the case along with their cumulative times. For a step to be included in the summary list, work must have been performed using the step. In most cases, work is performed when the treadle is depressed. Therefore, steps that are defined in the procedure but not actually used to perform work, are not listed. This could occur, for example, if the surgeon used the first step of a procedure, selected the second step but did not depress the

treadle, and then proceeded ahead to the third step to perform work. In this scenario, steps 1 and 3 would be included in the summary list, but step 2 would not be included in the summary since no work was performed with it.

In computing a step's cumulative time, it is necessary for work to be done while the step is selected in order for the current elapsed time to be added to the step's cumulative time. Therefore, a user may access a step and interact with the various touchscreen controls for an extended period of time but, unless the treadle is depressed, the current elapsed time will be discarded and will not be added to the step's cumulative time. If the step's cumulative time is zero, the step will not be shown in the step summary list.

Metrics Tabs

The End Case Metrics screens are accessed through the labeled tabs next to the Summary panel. Tabs are provided for Anterior, Posterior, Laser, and Consumables. When selected, each tab displays the associated metrics for that tab as shown by the Anterior tab in Figure 2-88. The Consumables tab displays all consumable items that have been detected by the system.

Setup Form

The End Case Form Settings screen shown in Figure 2-89 is displayed by pressing the Setup Form button on the End Case screen (Figure 2-88). The screen shows a picture of the End Case Form print-out and provides controls for navigating to other pages in the print-out, and for customizing the layout/content of the print-out.

The buttons at the bottom of the Form Settings screen perform the following actions:

- Page arrow buttons - Pressing these buttons allows the user to move through each page of the printout.



Figure 2-89 End Case: Setup Form Screen

- Save button - Pressing the Save button causes the system to save the various layout and content customization settings and return to the End Case screen.
- Cancel button - Returns the system back to the End Case screen without saving changes made to content and layout.

Setup Form: Editing the Form

To modify the form, press the Edit Form button. When pressed, the “smoked glass” panel is retracted allowing access to the various customization controls. The editing controls provide the following functionality:

- Cell navigation buttons including up, down, left, right.
- Cell text edit button.
- Drop list to permit the specification of a cell data fields.
- Cell appearance controls including font size and style, text alignment, and cell border lines (on/off).
- Table insertion/deletion controls
- Table row height, insertion, and deletion controls.
- Table column width, insertion, and deletion controls.
- Revert to Defaults button.

Setup Form: Editing the Form - Customizing Table Cells

The form is composed of a number of tables which are in turn composed of cells arranged in rows and columns. Each table cell provides various attributes that can be customized with respect to their appearance and content displayed. A cell can contain static text or it can be defined to include a data field whose text is determined at runtime. An example of a data field would be Surgeon Name.

To customize a cell follow these steps:

1. Select a table on the form by pressing on it. The table is then shown with selection handles. The active cell is shown in red.
2. Select the cell to be customized by using the Up, Down, Left, Right cell navigation buttons located in the Cell Selection & Edit panel.
3. To specify static text for a cell, press the Edit button (see Figure 2-89). When pressed, the keyboard popup is displayed allowing text to be entered by the user.
4. To specify a cell data field, press the Data Field drop list to display a list of available data field types including, but not limited to, Surgeon Name, Date, Procedure Name, etc. After selecting the desired data field, the associated data is automatically entered into the cell.
5. Specify the font and point size for a cell’s text using the Font, Font Style, and Font Size drop list controls. The Font Style drop list control is used to apply bold and italics formatting to the cell’s text.
6. Select the desired text alignment by pressing the Left Alignment, Center Alignment, or Right Alignment toggle buttons. The selected alignment will be highlighted.
7. Select the desired cell borders to show or hide by pressing the Bottom, Top, Left, or Right Border toggle buttons. If a border is on, it will be highlighted.

Setup Form: Editing the Form - Creating New Tables

To begin the customization process, the user must first select a table on the form by pressing on it. The table is then shown with selection handles and the active cell is shown in red.

To insert a new table after the selected table, follow these steps:

1. In the Table section of the Edit Form panel, press the Insert button (Ins). A table with two rows and three columns appears below the selected table and the new table is now the selected table. To delete the table, press the Delete button (Del).

The Table Type is selected from the Type dropdown list in the Table section of the Edit Form panel. The default table type for new tables is Custom which contains no entries or formatting (see Customizing Table Cells for information on editing individual cells).

2. Select the type of table desired from the Type dropdown list. There are five preformatted tables available from the list which automatically pull data from the procedures performed. The Custom selection allows the user to create a custom table to meet their particular requirements. Preformatted tables may also be customized according to the users requirements.
3. To increase the height of the selected row, press the Height% dropdown button and select an entry between 1 and 20%. The default row height is 2, so selecting 1 will result in a smaller row height and all selections above 2 will result in a larger row height. The height of the selected row is displayed on the Height% button.
4. To insert or delete a row, press the Ins (insert) or Del (delete) button in the Row section of the Edit Form panel.
5. To increase the width of the selected column, press the Width% dropdown button and select an entry between 5 and 100%. The default column width is 30, so selecting 5 through 25 will result in a smaller column width and all selections above 30 will result in a larger column width. The width of the selected column is displayed on the Width% button.
6. To insert or delete a column, press the Ins (insert) or Del (delete) button in the Column section of the Edit Form panel.

DEMO MODE

Demo Mode enables the user to navigate all available screens and simulate footswitch actions without connecting surgical tools (such as cassette, handpieces, probes, etc.) or source pressure. Demo Mode can be used to setup doctor and procedure settings that will automatically be transferred over for use in regular mode. Any changes made to existing doctor or procedure settings in Demo Mode will also carry over to the regular mode when the system is restarted.

TO ENTER DEMO MODE:

Press the Options button on the menu bar then press the Demo Mode button (shown in Figure 2-8); at the prompt, press “Yes” to enter Demo Mode. After 15-20 seconds, the Demo Mode Setup screen will appear as shown in Figure 2-90.

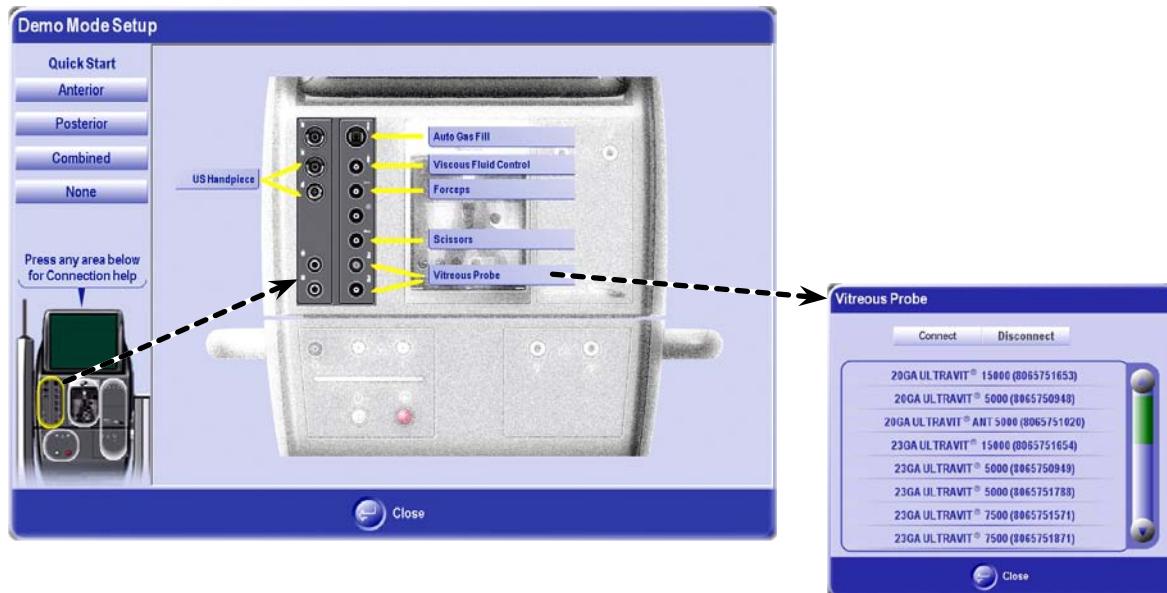


Figure 2-90 Demo Mode Setup Screen

SETTING UP DEMO MODE:

Pressing one of the selections under “Quick Start” connects all surgical tools associated with that type of procedure. For example, pressing the Anterior button results in a premium anterior cassette with automatic stopcock, anterior vitreous probe, and phaco handpiece being connected. The “connected icon”  will appear next to all connected instruments. Pressing the None selection disconnects all instruments.

Additionally, the user can select an area on the Connection help diagram. In Figure 2-90, the Left Connection Panel is selected and each instrument that can be connected to the panel is listed. Pressing on the instrument name displays a popup that allows the user to disconnect the current instrument and connect another from the list. After connecting the desired instruments press the Close button and the system displays the main screen as shown in Figure 2-91. The user can return to the Demo Mode Setup screen by pressing Options then Demo Options.

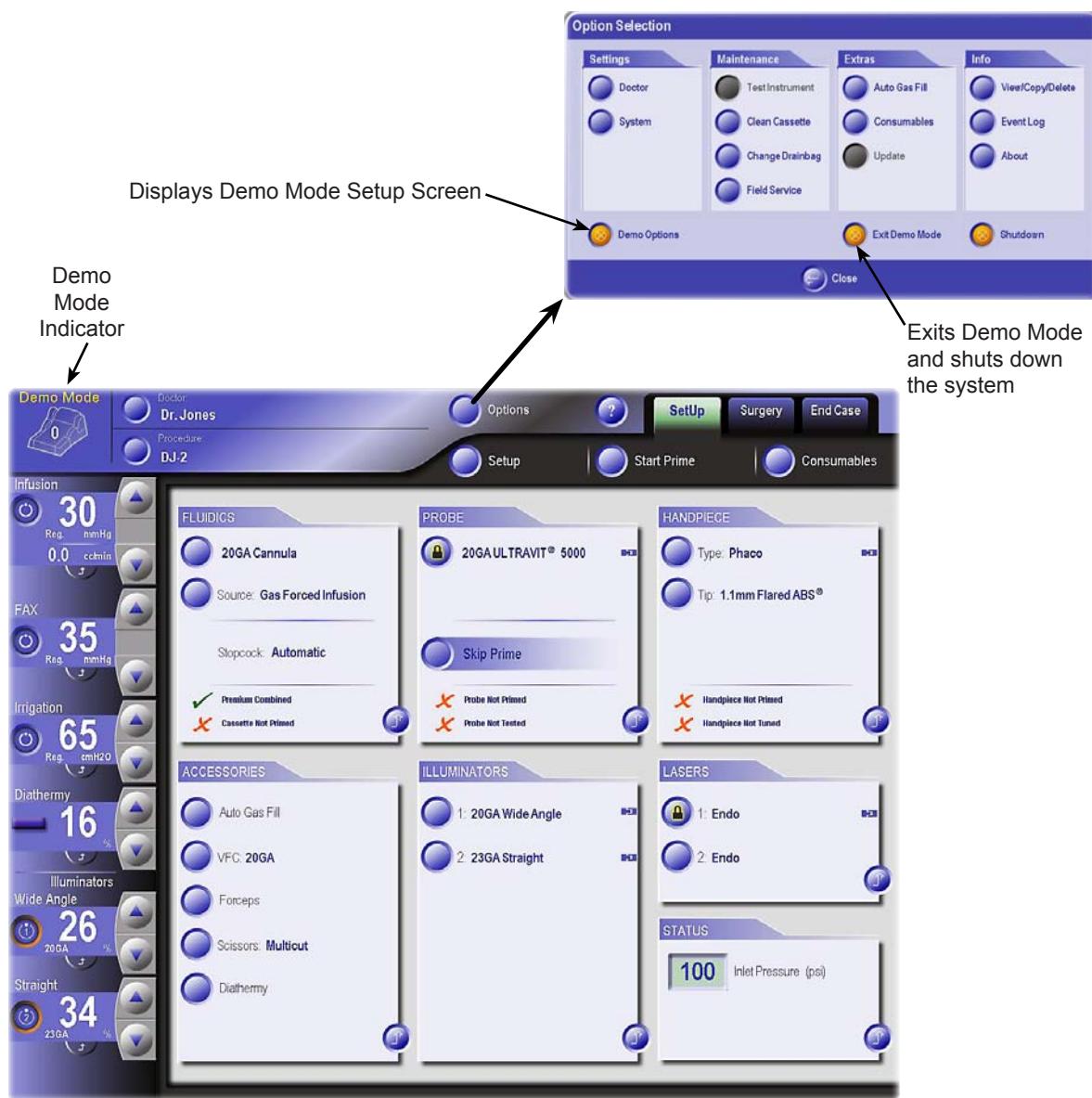


Figure 2-91 Demo Mode Main Screen

On the main screen, the “Demo Mode” label indicates that the system is in demo mode. This label is displayed in all Demo Mode screens: Setup, Surgery, and End Case screen.

USING DEMO MODE:

At this point the user can operate the user interface as if all connections performed in the setup screen are active. Actions that can be taken include:

- Settings can be changed via the global controls.
- Doctors and procedures can be added/edited.
- The system will simulate the priming sequence (by pressing the Start Prime button).
- Footswitch actions can be simulated.
- The simulated case can be reviewed in the End Case screens.

The footswitch simulator dialog is displayed by pressing the footswitch icon. It provides for the simulation of all footswitch functions using an onscreen interface. Once displayed, the popup can be repositioned to reveal the information on the underlying screen. Using the Simulator, the user can simulate footswitch button presses, treadle depression, and laser footswitch functions. Each of these functions is accessed by selecting the tabs shown in Figure 2-92.

Footswitch Simulator: Buttons - In order to simulate footswitch button presses, the Footswitch Mapping popup has been modified in Demo Mode to simulate footswitch button activation by pressing buttons on the popup window. For example, to activate Momentary Diathermy, press the associated button on the Footswitch Simulator and the Diathermy global control will be highlighted as if the footswitch button was pressed in normal operating mode.

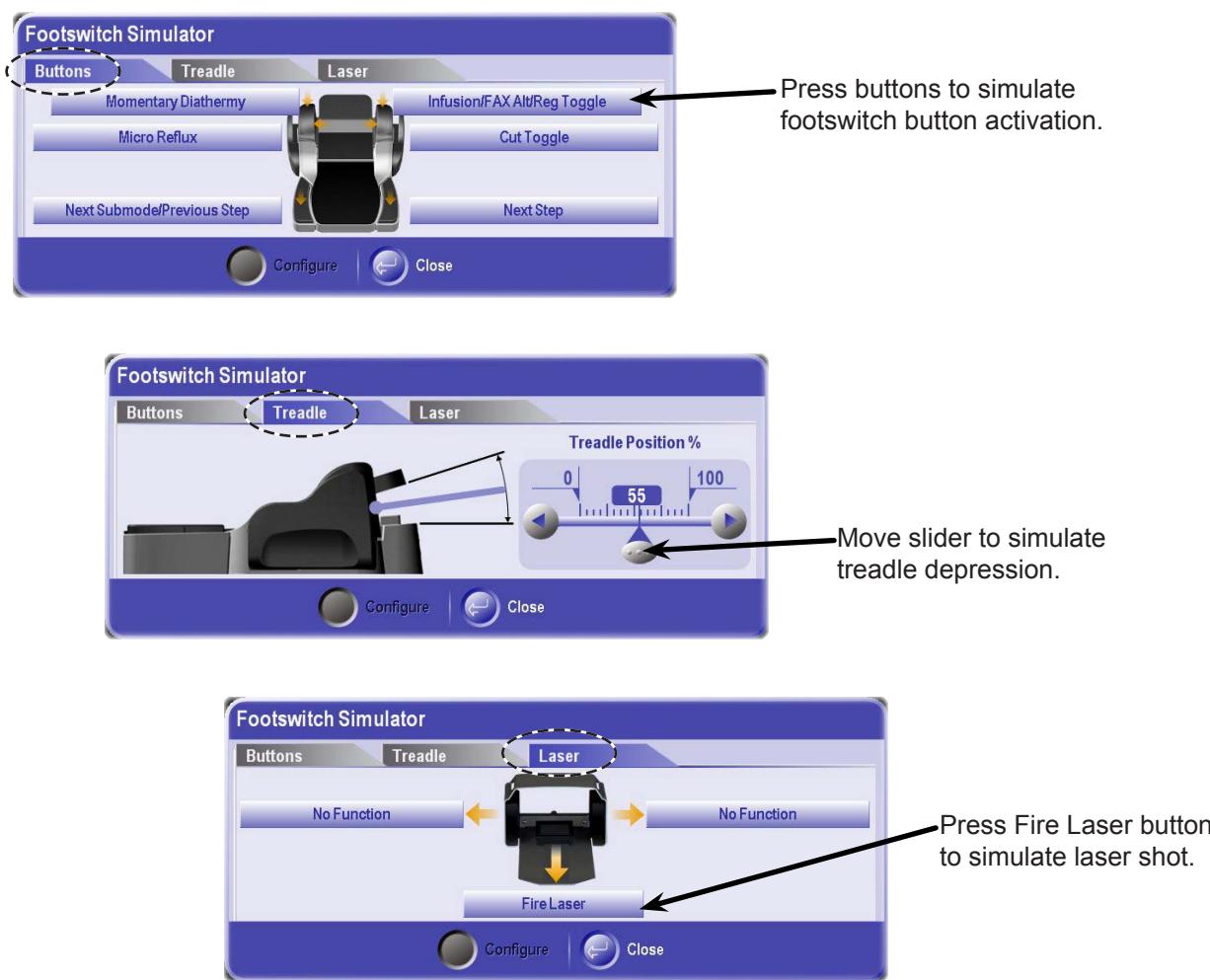


Figure 2-92 Footswitch Simulator Screens

Footswitch Simulator: Treadle - To simulate Treadle depression, select the Treadle tab then move the Treadle Position slider control. Figure 2-93 shows the effects of moving the slider in Vit 3D mode.



Figure 2-93 Footswitch Simulator Treadle Depression

Footswitch Simulator: Laser - To simulate firing the laser, place the system in Laser mode, select the desired settings, select “Ready” mode, and select the Laser tab on the footswitch simulator (see Figure 2-94).



Figure 2-94 Laser Footswitch Simulator

EXIT DEMO MODE

To exit Demo Mode, select Options from the Menu Bar then press “Exit Demo Mode.” The system will exit Demo Mode and shutdown. To restart the system in regular mode, press the Standby Switch on the rear panel.

PROBES AND HANDPIECES

NOTE: Refer to the Directions For Use (DFU) included with each accessory kit/consumable pack for detailed instructions on how to setup that accessory.

Different probes and handpieces are required for each operating mode of the *Constellation®* Vision System. Following is a representative selection of probes and handpieces with a general description of each. See the Accessories and Parts section of this manual, or consult your Alcon representative, for a complete selection of all probes, handpieces, and handpiece tips available. **NOTE: Please refer to Section One for a list of Warnings and Cautions that apply to the use and care of probes and handpieces.**

Vitrectomy Probes

- 20, 23, 25, 25+™, and 27+™ GA *UltraVit®* Probe
- 20 and 23 GA AVIT *UltraVit®* Probe



Figure 2-95 *UltraVit®* 20 GA Probe

Pneumatic Handle

The Pneumatic Handle is a multi-purpose tool that is designed to drive forceps or scissors tips. The console can drive these tips in multi-cut and proportional modes. When two handpieces are used, with one in the forceps location and one in the scissors position, they can be driven in the bimanual mode. Bimanual mode enables forceps activation during the first portion of footpedal travel and scissors activation during the second portion of footpedal travel.



Figure 2-96 Pneumatic Handle

Fragmentation Handpiece

The Fragmentation handpiece is configured to provide simultaneous vacuum and fragmentation, or vacuum only, depending upon the console setup. The handpiece has a stainless steel shell for improved reliability and durability. Other than attaching and removing the needle and aspiration line, no assembly or disassembly is required.



Figure 2-97 Fragmentation Handpiece

Phaco Ultrasound Handpieces

Alcon's phaco handpieces integrate irrigation, aspiration and emulsification. The three functions of the lens extraction step enable the surgeon to simultaneously maintain or inflate the anterior chamber, emulsify the lens, and aspirate the lens material from the eye. These handpieces require no disassembly other than removal of the disposable tubing, the ultrasonic tip, and the infusion sleeve with bubble suppression insert.

WARNINGS!

Appropriate use of **Constellation® Vision System** parameters and accessories is important for successful procedures. Use of low vacuum limits, low flow rates, low irrigation pressure, high power settings, extended power usage, power usage during occlusion conditions (beeping tones), failure to sufficiently aspirate viscoelastic prior to using power, excessively tight incisions, and combinations of the above actions may result in significant temperature increases at incision site and inside the eye, and lead to severe thermal eye tissue damage.

Directing energy toward non-lens material, such as iris or capsule, may cause mechanical and/or thermal tissue damage.

Use of an ultrasonic handpiece other than the **OZi®** torsional or the **U/S**, or use of a handpiece repaired without Alcon authorization, is not permitted, and may result in patient injury, including potential shock hazard to patient and/or operator.

Use of the **OZi®** torsional or the **U/S** handpiece in the absence of irrigation flow and/or in the presence of reduced or lost aspiration flow can cause excessive heating and potential damage to the cornea and other tissues.

During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.

CAUTIONS

Do not test or operate the **OZi®** torsional or **U/S** handpiece unless the tip is immersed in **BSS®** sterile irrigating solution or distilled water or is in surgical use. Irreparable damage to the handpiece and tip can result if run dry.

Ensure that test chamber is filled with **BSS®** sterile irrigating solution before tuning the **OZi®** torsional or **U/S** handpieces. Tuning a handpiece dry may result in premature tip failure and breakage.

- *Infiniti®* Ultrasonic (U/S) Handpiece - This handpiece is used for ultrasonic applications on the *Constellation®* Vision System with 1.1 mm *TurboSonics®* tips or 0.9 mm *TurboSonics®* tips, including flared and/or *ABS®* tips.

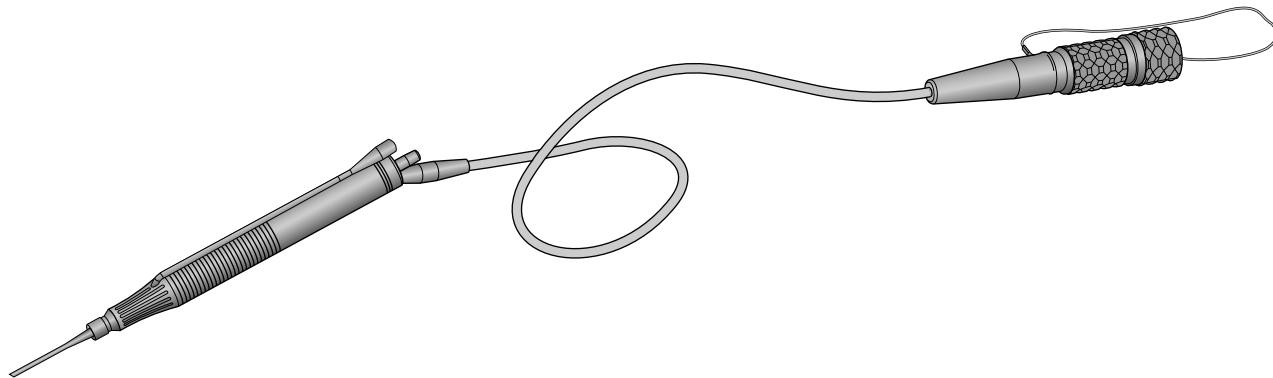


Figure 2-98 *Infiniti®* Ultrasonic (U/S) Handpiece

- *OZil®* Torsional Handpiece - The *OZil®* torsional handpiece integrates all functions of the ultrasonic handpiece, and in addition provides ultrasonic oscillations. This handpiece uses many of the same tips as the U/S handpiece; for best performance of *OZil®* torsional handpiece, use tips recommended by your Alcon representative.

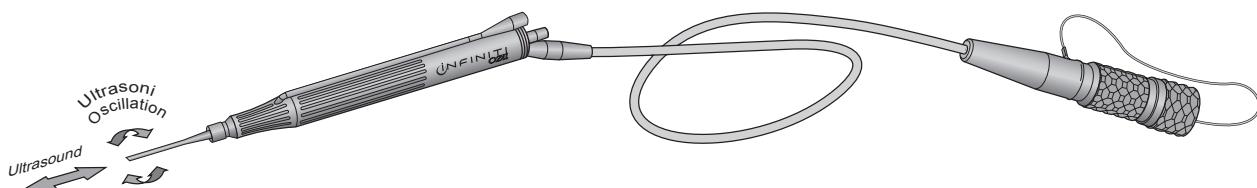


Figure 2-99 *OZil®* Torsional Handpiece

TurboSonics® Family of Tips

U/S tips are made of medical grade titanium alloy, and are attached to the *OZil®* torsional or U/S handpiece to deliver mechanical energy to the lens, assisting in its removal by aspiration. Depending on the needs and technique preferred by the surgeon, various styles of tips and tip bevels are available (see Figure 2-100). Various U/S tip styles are color coded.

- 1.1 mm U/S Tips - The standard ultrasonic tips are the original 1.1 mm *TurboSonics®* tips. They are designed for use only with 1.1 mm infusion sleeves.
- 0.9 mm U/S Tips - The 0.9 mm ultrasonic tips are designed to allow entry through a smaller incision. They are designed for use only with 0.9 mm infusion sleeves.
- Mackool** U/S Tips - The Mackool** ultrasonic tips contain a polymer tubing over the main part of the tip shaft. This necessary part of the Mackool** tip provides additional thermal and fluidic advantages.
- Aspiration Bypass System - The ABS® tip contains a small hole in the distal portion of the tip's wall. This helps to maintain flow through the system even during occlusion of the tip's main port.

WARNINGS!

Forphaco surgery, use only Alcon-certified *Turbosonics® MicroTip™* configurations (.9 mm). Alcon does not recommend the use of standard *Turbosonics®* tips (1.0 mm) with the *Constellation® Vision System*. The use of 1.1 mm phaco tips could result in undesirable fluidic instability. Please select irrigation and aspiration settings which are appropriate for the tip selected.

Poor clinical performance will result if tip is not secured tightly to the handpiece.

Read all information printed on the consumable packs prior to use.

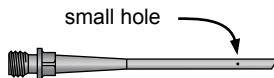
During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.



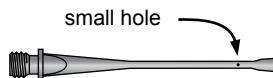
Standard U/S Tip - The 1.1 mm *TurboSonics®* tip with the round shaft is the original, classical U/S tip shape. The 0.9 mm has a smaller diameter shaft.



Kelman® Tip - The *Kelman®* tip has a bent shaft which generates transverse ultrasound motion, in addition to the conventional longitudinal motion, to enhance cutting efficiency. In addition, the bend allows better visibility during the surgical procedure.



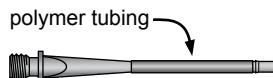
The Aspiration Bypass System - The *ABS®* tip contains a small hole in the distal portion of the tip's wall.



Flared ABS® Tip - The flared tip has a larger proximal port, providing increased holding force. They narrow in the middle of the shaft, thus allowing smaller incisions and improving occlusion breaks by reducing outflow from the anterior chamber, following occlusion breaks. Flared tips also have the Aspiration Bypass System feature, to further enhance performance.



Tapered Tip - The tapered *ABS®* tip is a combination of the 0.9 mm tip and the flared *ABS®* tip. The shaft inner and outer diameters is equivalent to straight tips, while the distal end is comparable to flared tips. The tapered *ABS®* tip has the improved holding force of a flared tip, and the same aspiration flow characteristics as a straight tip.



Mackool Series U/S Tip** - The *Mackool*** ultrasonic tip contains a polymer tubing over the main part of the tip shaft.

Figure 2-100 TurboSonics® Tips - Shown here are samples of U/S tips used with the *OZil®* torsional and the U/S handpieces.

MicroSmooth® Infusion Sleeves

Infusion sleeves cover the tip of the handpiece to provide irrigation to the anterior chamber of the eye during surgery (see Figure 2-101). Infusion sleeves are used with the *OZil®* torsional, the *Infiniti® U/S* handpiece, and with some *Ultraflow®* I/A handpieces. Infusion sleeves used with the *OZil®* torsional and *Infiniti® U/S* handpieces require a BSI (bubble suppression insert). Infusion sleeves must be correctly matched to the specific tip type (see the following descriptions).

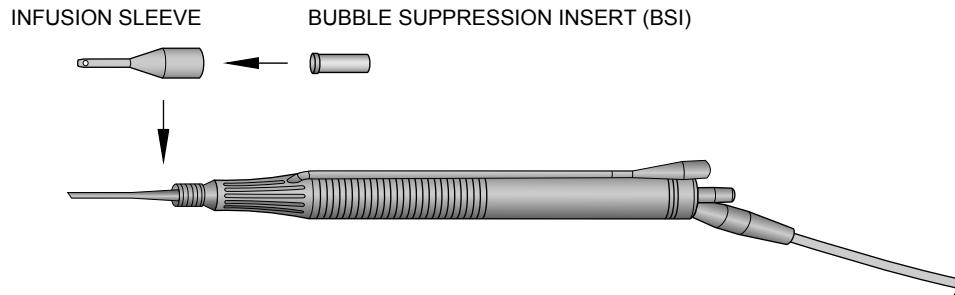


Figure 2-101 *Infiniti® U/S* Handpiece shown with Infusion Sleeve and Bubble Suppression Insert

Depending on the needs and technique preferred by the surgeon, various styles of infusion sleeves are available as listed in Table 2-3.

Table 2-3. MicroSmooth® Infusion Sleeves

| Infusion Sleeves | Sleeve Color | | Recommended Incision Size |
|-----------------------|-------------------------|-----------------------|---------------------------|
| | 0.9 mm | 1.1 mm | |
| High Infusion Sleeves | Semi-transparent purple | Semi-transparent blue | 3.2 mm |
| Standard | -- | Blue | 3.0 mm |
| Micro | Purple | Blue/green | 2.75 mm |
| Ultra | Red | Green | 2.2 mm |

Ultraflow® Handpieces and Tips

The *Ultraflow®* handpiece is used in I/A mode to maintain chamber pressure with irrigation while removing cortical material via aspiration. (See Figure 2-102 and note the band markings on the tips that identify size of tip aperture.) Some configurations of the *Ultraflow®* IT and SP handpieces also use infusion sleeves. The following *Ultraflow®* I/A handpieces and tips are available:

- *Ultraflow®* IT Handpiece and Interchangeable Tips - The *Ultraflow®* IT consists of a handpiece body that accepts interchangeable tips. These tips do not require an adapter or infusion sleeve as they contain a built-in metal infusion sleeve.
- *Ultraflow®* IT Handpiece and Threaded Tip Adapter - Reusable I/A tips with *TurboSonics®* silicone infusion sleeves can be used with the *Ultraflow®* IT handpiece with threaded tip adapter.
- *Ultraflow®* SP Handpiece (Single-Piece with fixed tips) - The *Ultraflow®* SP consists of a single-piece handpiece with irrigation tip, threaded tip adapter, or I/A tip with a built-in metal infusion sleeve. Various tip configurations are available.

WARNINGS!

Use of non-Alcon surgical reusable or disposable I/A handpieces that do not meet Alcon surgical specifications, or use of an Alcon handpiece not specified for use with the *Constellation®* Vision System, may result in a fluidic imbalance. This, in turn, may cause a shallowing or collapsing of the anterior chamber.

Exceeding the recommended level of 100 mmHg with a 0.5 mm or larger I/A tip may cause anterior chamber shallowing and/or incarceration or tearing of the posterior capsule.

I/A tips are not to be used with the *OZi®* torsional or U/S handpieces.

Constellation® Vision System

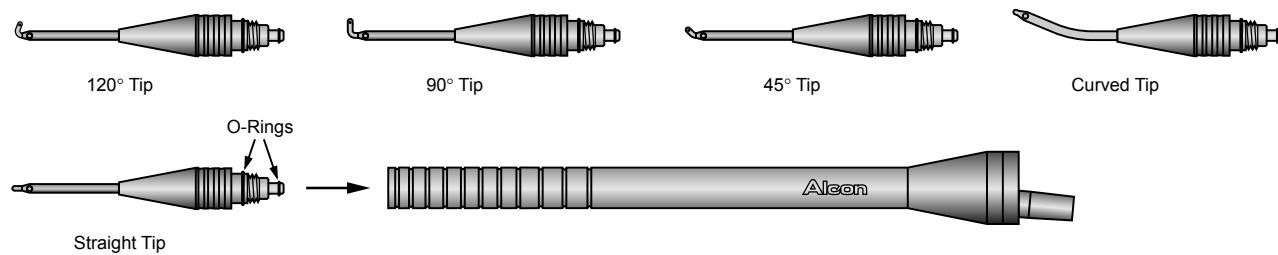


Figure 2-102 Ultraflow® IT handpiece and tips

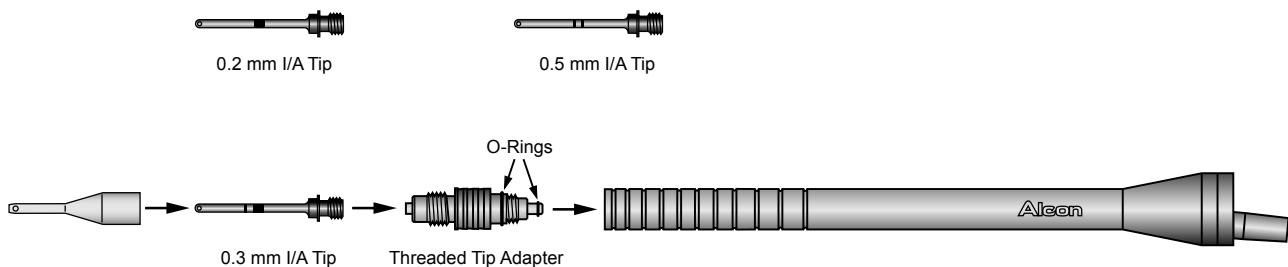


Figure 2-103 Ultraflow® IT handpiece with infusion sleeve, reusable I/A tip, and threaded tip adapter

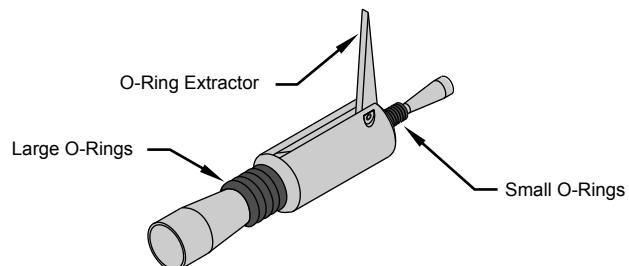


Figure 2-104 Ultraflow® O-ring tool with large and small O-rings



Figure 2-105 Ultraflow® SP handpiece (handpiece shown with .3 mm 45° tip)

Diathermy/Coagulation Handpieces

Single use Bipolar Coagulation Brushes are available in a wide variety of configurations: straight, curved, 20-gauge, 23-gauge, 25-gauge, 27-gauge, tapered, and widestroke. All single use bipolar accessories are available with and without cables. Also available are reusable and single-use bipolar cables.

Bipolar Coagulation Forceps are lightweight and ergonomically designed to reduce hand fatigue, as well as to provide precise control and safety. They are available in high-conductive non-stick alloy, titanium, or single-use configurations. They are also available with a wide variety of tip styles.



Figure 2-106 Single use bipolar brush

THE CONSTELLATION® CASSETTE

NOTE: Refer to the Directions For Use (DFU) included with each accessory kit/consumable pack for detailed instructions on how to setup that accessory.

The cassette is the interface between the *Constellation®* console and the surgical handpiece. It is used to regulate *BSS®* irrigating fluid to the handpiece, aspirate debris from the handpiece, monitor irrigation and aspiration pressure, and deposit the debris in a sealed drainage bag for disposal. The cassette ports are color coded and keyed for ease of identification and connection to the administration tubing sets. This will ensure proper connections each time the system is setup.

The premium combined cassette shown in Figure 2-107 is a consumable assembly capable of providing all the functions needed to perform anterior, posterior, and combined surgeries. It provides fluid aspiration and pressurized fluid (or filtered air) infusion to the eye at a constant IOP independent of aspiration flow rates during posterior segment surgery. The infusion fluid source to the cassette can be changed during a procedure without interruption or re-priming the tubing connecting the cassette and the infusion cannula.

Specialized cassettes for posterior and anterior procedures are available and have only those ports necessary to perform the associated procedure. See Consumable Pack Configurations on the following pages for detailed information on the type of cassette contained in each pack.

WARNINGS!

All fluids aspirated during surgery should be treated as biohazards. Take appropriate precautions when handling instruments and lines in contact with aspirated fluids.

Drain bag volume should not exceed 500 ml "Max. Capacity." Exceeding this volume may result in a biohazardous condition.

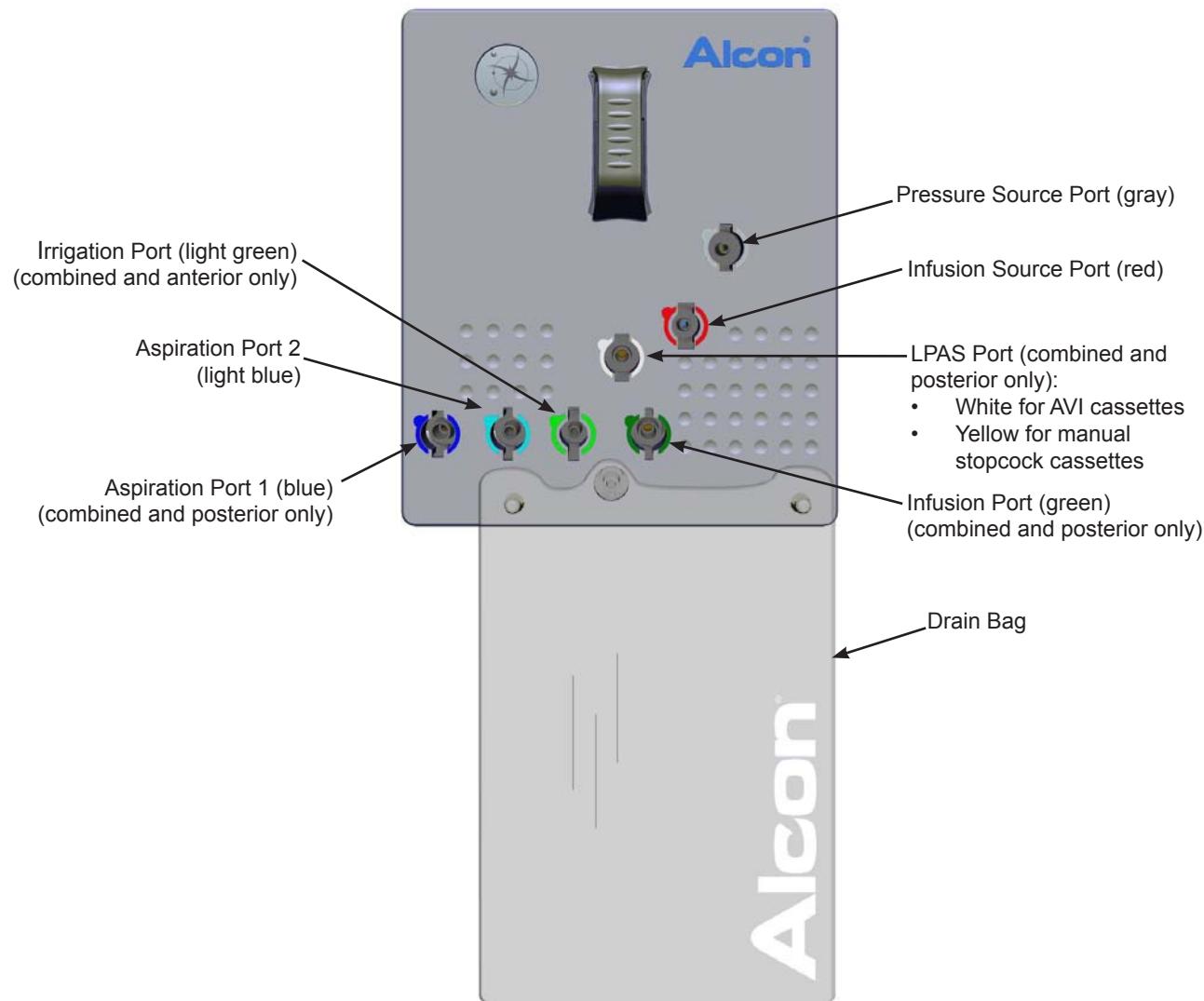


Figure 2-107 The Constellation® Combined Cassette

CONSUMABLE PACK CONFIGURATIONS

Constellation® Consumables Procedure Packs are available in multiple configurations to meet the user's needs for each procedure. There are three main types of Consumables Packs: Posterior segment, Anterior segment and Combined Procedure (both Posterior and Anterior).

The packs are available in various gauge/size offerings to suit the needs of the surgeon. The basic options for the *Constellation®* Consumables Procedure Packs are listed in Table 2-4. Contact your Alcon representative for available Pack configurations.

WARNING!

Attach only Alcon supplied consumables to console and cassette luer fittings. Do not connect consumables to the patient's intravenous connections.

NOTE: Refer to the Directions For Use (DFU) included with each accessory kit/consumable pack for detailed instructions on how to setup that accessory.

Table 2-4. Consumable Pack Contents

| ACCESSORY TYPE | PACK TYPE | | |
|--|---|---|--|
| | Combined | Posterior | Anterior |
| Cassette (Auto or Manual Stopcock) | <ul style="list-style-type: none"> Combined Procedure Cassette Premium Administration Tubing Set Premium Infusion FA/X Tubing Set Irrigation Aspiration Tubing Set | <ul style="list-style-type: none"> Posterior Cassette Premium Administration Tubing Set Premium Infusion FA/X Tubing Set Auxiliary Aspiration/Extrusion Tubing Set | <ul style="list-style-type: none"> Anterior Cassette Premium Administration Tubing Set Irrigation Aspiration Tubing Set |
| Vit Probe (20, 23, 25, or 27 GA) | <ul style="list-style-type: none"> 7500 cpm <i>UltraVit®</i> Probe 5000 cpm <i>UltraVit®</i> Probe | <ul style="list-style-type: none"> 7500 cpm <i>UltraVit®</i> Probe 5000 cpm <i>UltraVit®</i> Probe | -- |
| Endoilluminator Probes (20, 23, 25, or 27 GA) | <ul style="list-style-type: none"> Standard Endoilluminator Wide angle Endoilluminator | <ul style="list-style-type: none"> Standard Endoilluminator Wide angle Endoilluminator | -- |
| Posterior Accessories (20, 23, 25, or 27 GA) | <ul style="list-style-type: none"> High flow infusion cannula Posterior Small Parts Kit MVR Blade (20 GA only) Standard (23/25 GA) or Valved Entry System (23/25/27 GA) | <ul style="list-style-type: none"> High flow infusion cannula Posterior Small Parts Kit MVR Blade (20 GA only) Standard (23/25 GA) or Valved Entry System (23/25/27 GA) | -- |
| Anterior Accessories (0.9 mm or 1.1 mm) | <ul style="list-style-type: none"> Anterior Small Parts Kit | -- | <ul style="list-style-type: none"> Anterior Small Parts Kit |

SECTION THREE OPERATING INSTRUCTIONS

INTRODUCTION

This section details the recommended initial setup for the *Constellation®* Vision System. These procedures may be modified to conform to hospital requirements and practices as you become experienced in using the system.

The procedures are divided into two columns and presume a surgical team of three people: Surgeon and Scrub Nurse in the sterile field, and a Circulating Nurse in the non-sterile field. In the left column a directive is given; in the right column the responsible team member is identified.

Any problems pertaining to setup and check-out procedures should first be directed to the Troubleshooting section of this manual. If questions still exist, contact the Alcon Technical Services Department or your local Alcon representative.

For accessory setup and use information, please refer to the "Directions for Use" included with each accessory. In addition, the *Constellation®* Vision System contains setup Help videos that can be accessed by pressing the Help button located at the bottom of each setup screen.

POWER UP SEQUENCE

When the power switch is turned on, and the standby switch is pressed, the *Constellation®* Vision System logo screen appears while the system performs its self-test diagnostics. The system is capable of detecting and reporting a wide range of advisories, errors, and faults. Many of these are checked during the power up procedure. If an operational condition is detected during power up, the user is informed and the instrument becomes non-operational until the advisory, error, or fault is corrected. Upon successful completion of the self-tests, the system enters the setup screen.

Table 3-1. INITIAL SYSTEM SETUP

| | |
|---|-------------------|
| <p>1. Position the system and the optional instrument tray as required for the procedure to be performed. For additional information, refer to the procedure "Positioning the Instrument Tray" later in this section of the manual. NOTE: The instrument tray height should be positioned so that it is approximately at mid-cassette level.</p> | Circulating Nurse |
| <p>2. Constellation® Footswitch: Connect the Constellation® footswitch by matching the red dot on the footswitch cable connector to the red dot on the footswitch, plug cable into footswitch. Plug the other end of the footswitch cable into the rear panel on the console or on the front of the optional base (match red dots for proper orientation). Note: Only the Constellation® footswitch should be used with the Constellation® Vision System.</p> <p>Laser Footswitch: If the optional laser will be used in the procedure, connect the laser footswitch to the Constellation® Vision System rear panel (see Figure 2-2 for rear panel connections). If the laser will be tethered to the Constellation® console, refer to the procedure "Connecting a PurePoint® Laser to the Constellation® Vision System in Tethered Mode" later in this section of the manual.</p> | Circulating Nurse |
| <p>3. Connect pressure source to rear panel as described in the procedure "Connecting the Constellation® Vision System to a Facility Pressure Source" in this section of the manual.</p> | Circulating Nurse |
| <p>4. If the Video Overlay feature will be used, connect the external equipment as shown in Figures 3-7 or 3-9.</p> | Circulating Nurse |
| <p>CAUTION</p> <p>Do not use portable socket outlets or power strip with this system.</p> <p>4. Plug main power cord into a suitable wall outlet or receptacle. Turn Power switch located at the bottom of the rear panel next to the power cord, to the On position (this switch remains ON in the "I" position). Turn system power ON by pressing the Standby switch located at the middle of the rear panel.</p> <p>The Setup screen appears if this is the first use of the instrument after power up. Refer to Section Two for a detailed description of the screens displayed during setup.</p> | Circulating Nurse |
| <p>5. Press the Doctor button and select an available doctor, or add a doctor by following the steps presented on the display.</p> | Circulating Nurse |

Table 3-1. INITIAL SYSTEM SETUP

| | |
|---|-------------------|
| <p>6. Scan the pack or select the appropriate handpiece, tip, accessories, and procedure types. The following accessories have been designed for use with the <i>Constellation®</i> Vision System:</p> <ul style="list-style-type: none"> • <i>Constellation®</i> Procedure Packs • Auto Gas Filler Pack • Fragmentation Pack • Viscous Fluid Control Pack • Extrusion Accessories • Fiber Optic Illuminator Accessories • Diathermy Accessories • Pneumatic Handpiece Accessories <p>NOTE: Refer to the Directions For Use (DFU) included with each accessory kit/consumable pack for detailed instructions on how to setup that accessory.</p> | Circulating Nurse |
| <p><u>CAUTION</u></p> <p>U/S and fragmentation handpieces must be at room temperature before use. Allow handpiece to air cool after steam autoclave (at least 15 minutes). Never immerse in liquid to cool.</p> <p>7. Sterilize the instruments according to hospital procedure (refer to Section Four for additional cleaning/sterilization information).</p> | Circulating Nurse |

POSITIONING THE INSTRUMENT TRAY

The tray is capable of accommodating a variety of positions in the operating room environment: right, left, front and rear of the surgeon as well as the front of the bed. In addition, the tray can be installed on either side of the system. The tray height and position are adjustable by pulling the Instrument Tray Latch Release shown in Figure 3-1.

WARNING!

The maximum allowable load on the instrument tray is 20 lb (9 kg). If the load exceeds this limit, the tray arm will automatically lower itself in order to avoid tipping the system over. Additionally, if the instrument tray is positioned over a patient, a mayo stand should be placed beneath it to avoid a potential collapse of the tray arm onto the patient.

NOTE: The Instrument Tray may be installed on either side of the system.

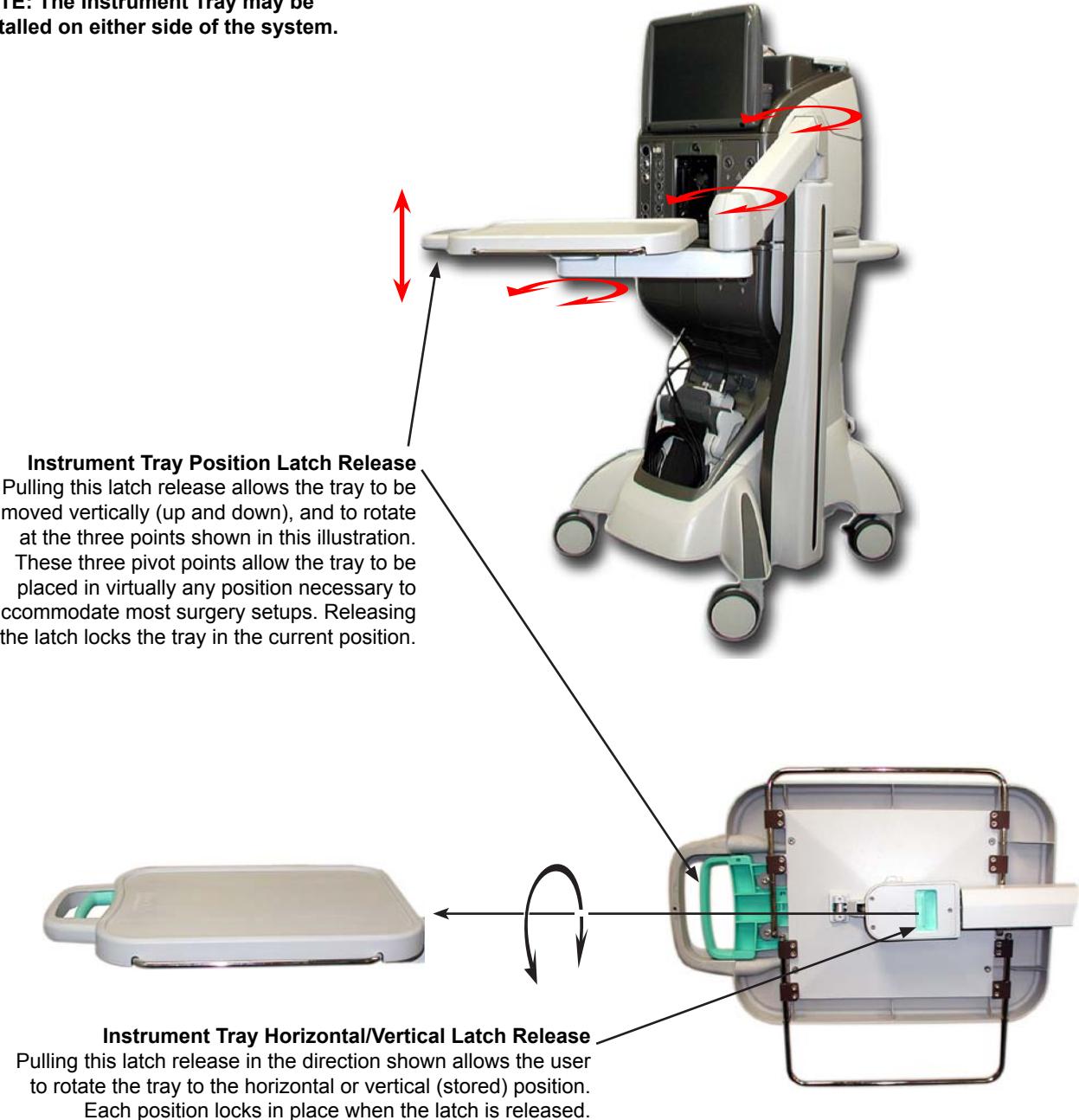


Figure 3-1 Positioning the Instrument Tray

Placing the Instrument Tray in the Stored Position

WARNING!

Place the instrument tray in the stored position (see Figure 3-2) prior to transportation to avoid a situation that could cause the system to tip.

- 1 Pull the Horizontal/Vertical Latch Release (see Figure 3-1) and rotate the instrument tray to the vertical position shown in Figure 3-2.
- 2 Pull the Position Latch Release and move the tray and arm assembly into the stored position shown in Figure 3-2.

Instrument Tray in the vertical position



Instrument Tray/Arm in the stored position



Figure 3-2 Storing the Instrument Tray

CONNECTING THE CONSTELLATION® VISION SYSTEM TO A FACILITY PRESSURE SOURCE

Notes:

- To ensure proper function of the *Constellation®* Vision System, all pressure source fittings and hoses used must have a minimum of 1/4 inch inside diameter like the Alcon supplied fittings and hose.

CAUTION

If smaller ID fittings are used in conjunction with the inlet hose fittings, system performance may be affected at “Minimal Inlet Pressure” (58.8 to 72.5 psig).

- Use thread sealant when connecting fittings.

AIR Pressure Source Configuration

The pressure hose is shipped in a configuration that is compatible with some facility air pressure source fittings. The shipped configuration is shown in Figure 3-3.

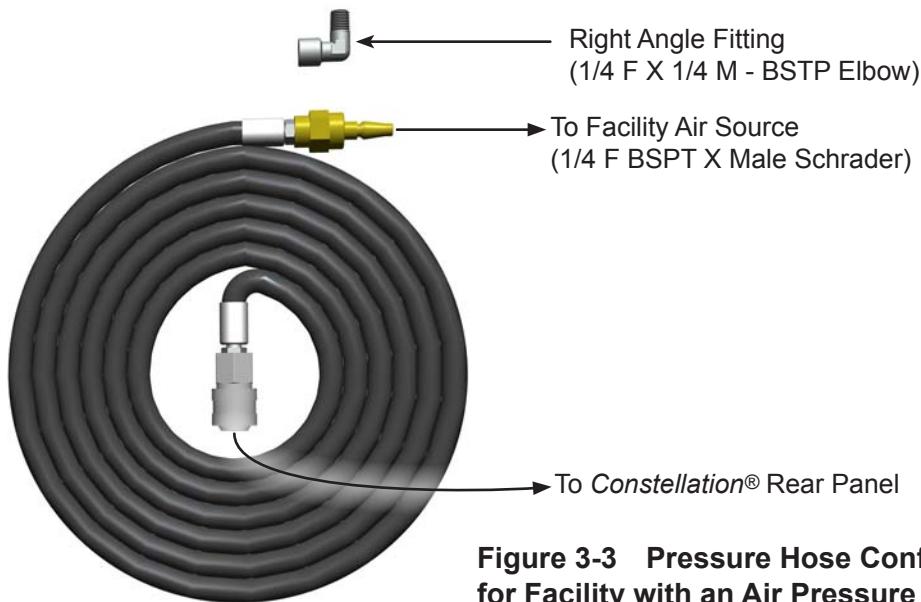


Figure 3-3 Pressure Hose Configuration for Facility with an Air Pressure Source

To connect the *Constellation®* Vision System to a facility air pressure source, perform the following steps:

- 1 Determine if facility air pressure source is compatible with the provided hose configuration.
- 2 Connect hose to the facility air pressure source.
- 3 Connect the quick disconnect fitting to the *Constellation®* Vision System rear panel.

Note: A right angle fitting is included with the hose assembly and may be used to replace the fitting on the *Constellation®* Vision System rear panel if desired. In this configuration, remove the quick disconnect fitting from the hose then thread the hose onto the right angle fitting on the rear panel (no quick disconnect).

INSTALLATION AND REPLACEMENT OF ISPAN* GAS BOTTLES

The following instructions detail the installation and replacement of the IS PAN* gas bottles that support the Auto Gas Fill functionality of the *Constellation®* Vision System equipped with optional base unit. **NOTE: The IS PAN* gas bottle and console connection are uniquely configured and color coded for each type of gas to prevent misconnection.**

Installation of IS PAN* Gas Bottle

- 1 Place the included o-ring (o-ring for SF₆ only) in the regulator fitting and attach the regulator(s) to the appropriate gas bottles via the threaded compression fitting (see Figure 3-4). Using a wrench, carefully tighten regulators to tanks. The specified gas is labeled on the body of each regulator.



Figure 3-4 Connecting the Regulator to the IS PAN* Gas Bottle

- 2 Place the bottle/regulator assembly in the IS PAN* Gas Tank Holder on the rear of the base unit (see Figure 3-5). Fasten the clip on the tank holder to secure the bottle assembly.
- 3 Locate the Auto Gas Fill tubing set at the rear panel of the system.
- 4 Attach appropriate quick-connect fitting from the tubing set on the rear of the table top console to the regulator. These connectors are color-coded and configured to prevent misconnection.
- 5 Ensure the Auto Gas Fill tubing set is connected to the AGF Tank Connector on the rear panel of the table top console.
- 6 Open the valve on the bottle by rotating the colored handle counterclockwise. **NOTE: The pressure regulators are pre-set at the factory and do not need user adjustment.**

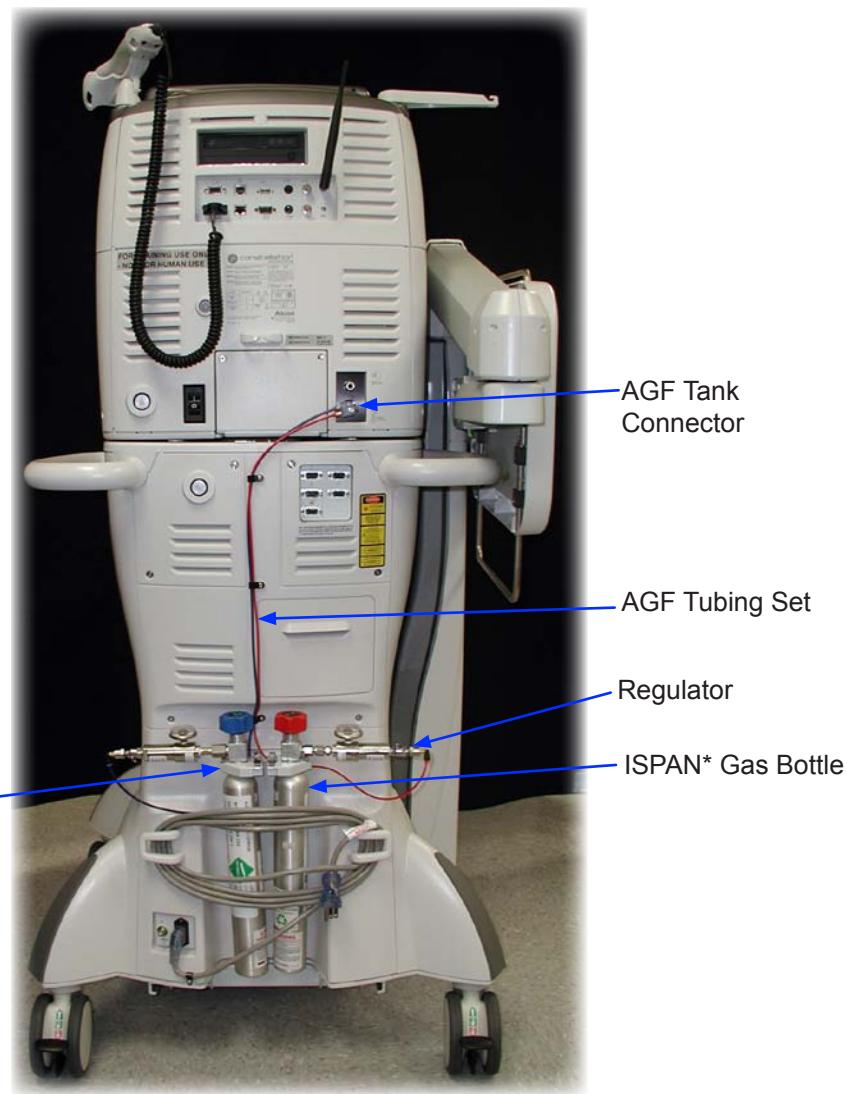


Figure 3-5 Installed ISPAN* Gas Bottles

Removal of ISPAN* Gas Bottle

- 1 Ensure the valve on the gas bottle is fully closed by rotating the colored handle clockwise.
- 2 Disconnect the regulator from the AGF tubing set by disconnecting the quick connect fitting at the tubing to regulator interface. **NOTE: A small amount of residual gas may exhaust from the line during disconnection.**
- 3 Remove the gas tank from the ISPAN* Gas Tank Holder by loosening the retainer clip.
- 4 Remove the gas tank from the regulator by loosening the threaded compression fitting. Be sure to save the o-ring (SF₆ only).
- 5 Dispose of the empty gas tank in accordance to the special disposal instructions indicated on the gas tank.

CONNECTING A PUREPOINT LASER TO THE CONSTELLATION® VISION SYSTEM IN “TETHERED” MODE

If the system does not contain the optional laser module, an Alcon *PurePoint®* Laser can be connected (tethered) to the *Constellation®* Vision System using an ethernet cable. In this configuration, the *Constellation®* system console has functional control over the laser and the systems function as if the optional laser module is installed. To connect the *PurePoint®* Laser and the *Constellation®* Vision System, perform the following steps:

1. Ensure that both systems are OFF.
2. Connect the laser footswitch, Dr. filter, remote interlock, laser status, and laser delivery devices to the *PurePoint®* Laser console as described in the *PurePoint* Operator’s manual.
3. Connect an ethernet cable between the “Tether Port” on the *PurePoint* Laser rear panel and the “Tethered Laser” port on the *Constellation®* Vision System rear panel.
4. Turn the *Constellation®* Vision System ON.
5. Turn the *PurePoint®* Laser ON. The *PurePoint* Laser will turn on but the screen will remain blank.

All changes to the laser setup and adjustments to the various laser parameters are made through the *Constellation®* system touch screen. For additional information, refer to the Laser Setup Panel and the Laser Mode Surgery screen later in this section of the manual.

NOTE: In tethered mode, all *PurePoint®* Laser front panel controls except for the emergency switch are disabled.

VIDEO OVERLAY

The *Constellation®* Vision System can be configured with either a Standard Definition or a High Definition Video Overlay card. The video overlay screen layout and content vary depending on which type of video overlay card is installed in the system.

Standard Definition Video Overlay

The standard definition video overlay screen shown in Figure 3-6 consists of four main areas:

- **Header** - The header is displayed along the top of the screen.
- **Globals** - Globals are displayed on the left side of the screen. Setpoints are displayed in off-white text when globals are off. Actual values are displayed in blue when globals are on.
- **Surgical Values** - Surgical values are displayed on the right side of the screen and are dependent on the current mode/submode. When treadle is NOT depressed, setpoint values are displayed in off-white text. If the Start and End setpoint values can be changed, both setpoint values are displayed. If the control type is fixed, or only the End setpoint value can be changed, only the End setpoint value is displayed. When treadle is depressed, actual values are displayed in blue.
- **Indicators** - There are four indicators displayed in the lower-center part of the screen to indicate the status of Reflux, Laser Ready or Firing, and Video Recording.

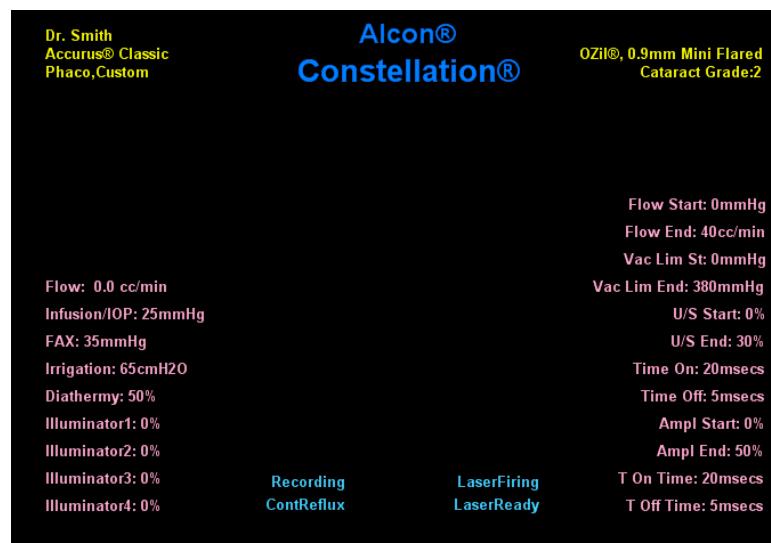


Figure 3-6 Standard Video Overlay Screen

Standard Definition Video Overlay Connections

Refer to Figure 3-7 for connecting a camera, video recorder, and monitor to a *Constellation®* Vision System configured for a Standard Definition Video Overlay.

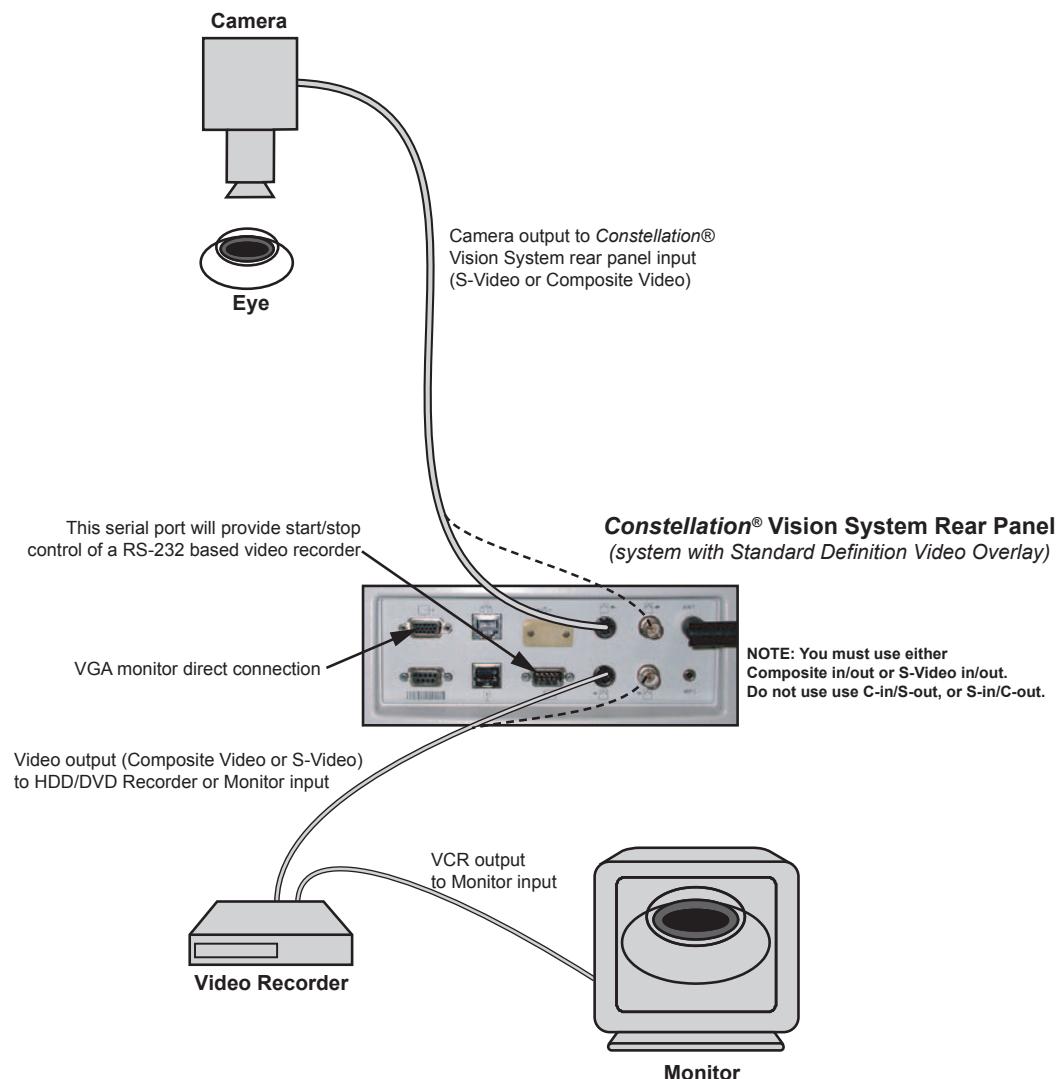


Figure 3-7 Standard Definition Video Overlay Connection Diagram

High Definition Video Overlay

The high definition video overlay screen shown in Figure 3-8 consists of five main areas:

- **Header** - The header displayed along the top of the screen includes the Alcon and *Constellation®* Vision System logos.
- **Footer** - The footer is displayed along the bottom of the screen. The content of the center area of the footer alternates between displaying doctor, procedure, and step name (when applicable). The footer is removed after the system has gone through one complete footer display cycle and is displayed again when the system enters a new mode or submode, or a user action causes any of the data fields in the footer to be refreshed.
- **Globals** - Global control values are displayed on the left side of the screen. Global values are only displayed when the corresponding global function is turned on.
- **Surgical Values** - Surgical values are displayed on the right side of the screen and are dependent on the current mode/submode. Both the Start and End setpoint values are displayed for progress bar controls. When the treadle is NOT depressed, or for a momentary surgical function the corresponding footswitch button is not pressed, 0 is displayed. When the treadle or footswitch button is depressed, the actual values are displayed in a larger font size and the progress bar is updated according to the current treadle position.
- **Indicators:**
 - *Footswitch* - A Footswitch icon is displayed in the top left corner of the screen. The current treadle position is displayed in the center of the icon. When a footswitch switch is depressed, an arrow is displayed next to the corresponding switch.
 - *Laser State* - The current state of the Laser is indicated on the Laser surgical control on right side of the screen in Laser modes. When the Laser transitions between Standby, Ready, and Firing states, the displayed text on the Laser control is updated and the background color is changed to match the new state of the Laser.

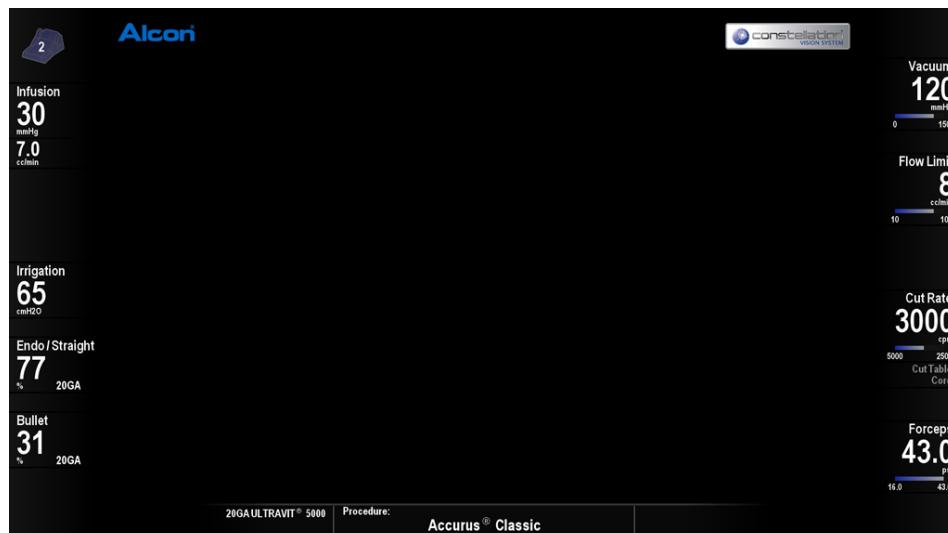


Figure 3-8 High Definition Video Overlay Screen

- **Status** - The Status Area is located in the bottom left corner of the screen and displays the status of the following items: Occlusion, Diathermy, Micro-Reflux, Proportional Reflux, and Continuous Reflux.

High Definition Video Overlay Connections

Refer to Figure 3-9 for connecting a camera, video recorder, and monitor to a *Constellation®* Vision System configured for a High Definition Video Overlay.

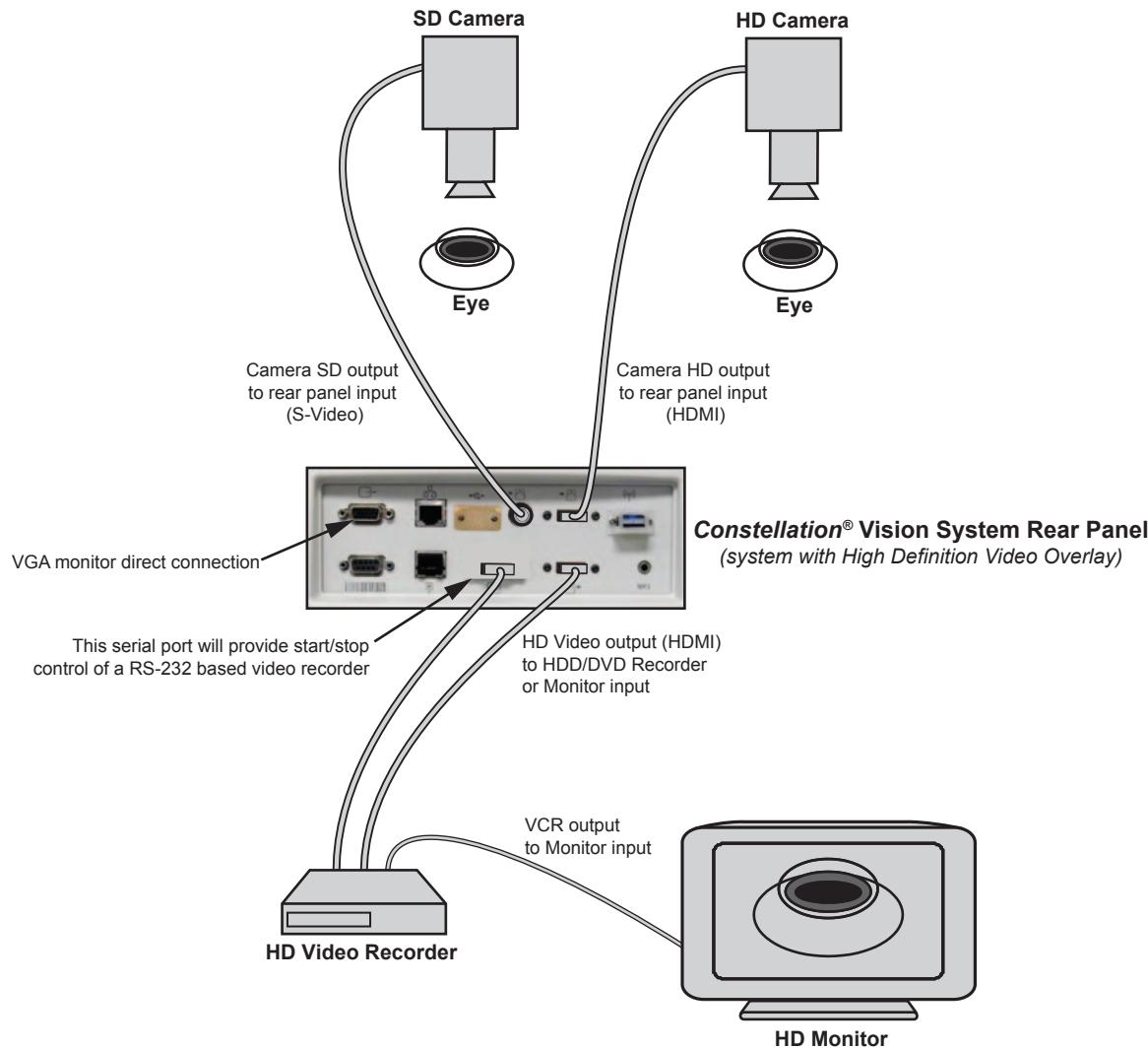


Figure 3-9 High Definition Video Overlay Connection Diagram

The Video Recorder is a separate piece of equipment supplied by the customer. The video recorders listed below are the only recorders approved for use with *Constellation®* Vision System.

- Sony Medical Grade DVD Recorder P/N DVO-1000MD
- Sony Medical Grade DVD Recorder (high definition) P/N HVO-1000HD

Sony Electronics Inc. - Medical Systems Division
1 Sony Drive, Park Ridge, NJ 07656-8003

CONSTELLATION® PROCEDURE PACK

Constellation® Procedure Packs are available in three (3) procedural pack configurations: *Constellation®* Vitrectomy Pack, *Constellation®* Phaco Pack, and *Constellation®* Combined Procedure Pack. Each pack contains the sterile single-use supplies necessary to perform one Posterior segment, Anterior segment, or Combined Procedure respectively. The Combined Procedure covers both Anterior and Posterior segment procedures.

WARNINGS!

1. If any item in the pack is received in a defective condition, Alcon is to be notified immediately. Do not use any of the contents if the sterile package is damaged or the seal is broken in any way. In these cases, please contact:

By Phone:

In USA (800) 757-9780

Ask for Medical Safety

International (817) 293-0450

Or contact local Alcon Representative

By Mail:

Alcon Research, Ltd

Attention: Medical Safety (AB2-6)

6201 South Freeway

Fort Worth, TX 76134-2099

USA

By E-mail: MedicalSafetyHouston@alconlabs.com

Each pack is identified by a lot number which provides traceability and should be given to Medical Safety Department when discussing the pack.

2. Improper usage or assembly could result in a potentially hazardous condition for the patient. Mismatch of consumable components and use of settings not specially adjusted for a particular combination of consumable components may create a patient hazard.
3. Visually confirm that adequate infusion flow is occurring prior to attachment of the infusion cannula to the eye.
4. Do not operate Vitrectomy probes in air. This could result in performance degradation and/or potential hazard.
5. Replace Vitrectomy Probe if any of the following conditions are observed:
 - a. Excessive air bubbles are in the aspiration line.
 - b. Air bubbles are exiting the cutter port.
 - c. The cutter does not fully close or does not move when the probe is actuated.
 - d. The cutting port is not open when the probe is idle.
 - e. If a reduction of cutting capability or vacuum is observed during the surgical procedure, stop immediately and replace the probe.
6. Minimize the light intensity and duration of exposure to the retina to reduce the risk of retinal photic injury.
7. Use of incisions that are smaller than recommended during lens removal can lead to mechanical and/or thermal damage to the eye tissue.

SECTION FOUR CARE AND MAINTENANCE

INTRODUCTION

This section of the manual is designed to inform the operator of basic care and maintenance of the instrument. If a problem occurs on the instrument, call the Alcon Technical Services Department and give details of the breakdown circumstances and effects. From these elements, a specialized technician will evaluate the problem and determine the maintenance requirements.

For optimum performance, it is the user's responsibility to schedule preventive maintenance service on the system and its accessories at least two times each year. Alcon's Field Service Engineers are trained and equipped to provide the highest quality of workmanship.

CAUTION

There are no operator replaceable parts, including the illuminator lamps. Contact Alcon Technical Services for all servicing issues.

WARNING!

The Constellation® Vision System battery can only be serviced by a factory-trained Alcon service personnel. Access by untrained personnel can lead to injury.

CARE AND CLEANING

The following recommendations are for proper care of the *Constellation® Vision System*:

- Follow cleaning and maintenance schedules outlined in this section of the manual.
- Periodically check chassis appearance.
- Pay attention to correct operation of controls, connectors, and indicators.
- Damaged hardware must be replaced to ensure safe operation. Call Alcon Technical Services for assistance.

WARNING!

A qualified technician must perform a visual inspection of the following components every twelve months:

- Warning Labels (see section one of this manual)
- Power Cord

In case of a deficiency, do not use the system; call Alcon Technical Services.

A qualified technician must check ground continuity for leakage current every twelve months to ensure they are within the applicable standards (for example: EN60601-1/IEC601-1). Values must be recorded, and if they are above the applicable standards, do not use the system; call Alcon Technical Services.

UPON COMPLETION OF THE PROCEDURE

CAUTION

Do not remove tubing from cassette or fluid in cassette reservoirs will leak down front of machine.

- 1 Select End Case - Press End Case tab at top right corner of screen. The system will confirm that you want to end the case. Select Yes or No.
- 2 Ensure infusion clamp is closed and turn Infusion off - Press “Infusion” icon at top left corner of screen to turn infusion off. The system will confirm that you want to turn off infusion. Select “Continue” and the cassette will start the cleaning process.
- 3 Once cleaning is complete, remove irrigation bottle from hanger and set aside. Remove spike from irrigation bottle.
- 4 Push ejection button above cassette to remove. Discard cassette with tubing per facility guidelines.
- 5 Move the irrigation bottle holder to its storage position.
- 6 Press Standby switch located at top of rear panel (or Shutdown in Options menu) to remove operating power from the system.
- 7 Turn the Main power switch OFF. It is located in the middle of the rear panel above the power cord.
- 8 Remove air hose. Turn off C3F8 and SF6 valves.
- 9 Disconnect the power cable from the wall receptacle and wind the cable around the cord wrap.
- 10 Place the footswitch and cable in storage compartment in front of base.
- 11 If required, the front panel, the console, the footswitch, and the remote control may be wiped with non-corrosive germicidal solution, alcohol, or mild soap and water.

CAUTIONS

- **Do not clean console or accessories using solvents or abrasives.**
- **Avoid spilling *BSS*® solution, or moisture of any kind, around the electrical handpiece connectors.**

- 12 Clean handpieces, probes, cables, forceps, etc., as instructed in DFU's supplied with each accessory.

STERILIZATION INSTRUCTIONS

Please consult the accompanying Directions For Use (DFU) for cleaning and sterilization instructions for Alcon approved reusable accessories. The DFU will provide the recommended time and temperature guidelines for steam autoclave cycles performed by Alcon, Inc. **The sterility assurance level achieved with these parameters must be validated by each surgical facility.** Please refer to Association for the Advancement of Medical Instrumentation (AAMI) Standards or your facility's standard procedures for the most current specifications.

Additionally, per the Sterilizer Equipment Manual, the sterilizer reservoir is to be filled with distilled or deionized water.

NOTE: The reusable items will withstand steam autoclave cycles at 134° C (273°F). Due to the variations found in steam autoclaves and the variable bioburden on devices in clinical use, it is not possible for Alcon to provide specific parameters to ensure an adequate sterility assurance level. Validation of the individual autoclave, and verification of the sterility assurance level achieved with a given steam sterilization cycle, must be performed by each surgical facility. Please refer to below AAMI Standards or your facility's standard procedures for the most current specifications.

DISPOSAL OF XENON LAMPS

WARNING!

The bulb of the xenon lamp is under constant high pressure. There is a risk it may burst with explosive force if knocked or damaged. Protective measures:

- Keep the lamp in its protective sleeve at all times during installation
- If you are handling the lamp without its protective sleeve, always wear safety goggles, a face mask, gauntlets with wrist protectors and a breast protector.

In the USA contact the Alcon Technical Services Department for lamp disposal at 800/832-7827. Outside the USA contact your local Alcon affiliate.

REPLACEMENT OF REMOTE CONTROL BATTERIES

WARNING!

Changing batteries will cause the remote to default to channel A; therefore the remote may need to be reset to the instrument's unique channel after installing new batteries.

- 1 Loosen two captive screws on the rear cover with a standard slotted screwdriver and remove cover.
- 2 Replace old batteries and replace cover (correct battery positions are identified inside each battery slot). When closing the cover it is important that the rubber buttons slide into the slots in other half of the remote without binding (see Figure 4-1).
- 3 To check correct installation of batteries, press a backlight button on the side of the remote and verify that the remote control buttons illuminate, then turn off after a few seconds. If illuminated buttons don't turn off, rubber buttons are not properly inserted into slots, so you must repeat the procedure.
- 4 Dispose of batteries following local governing ordinances and recycling plans.

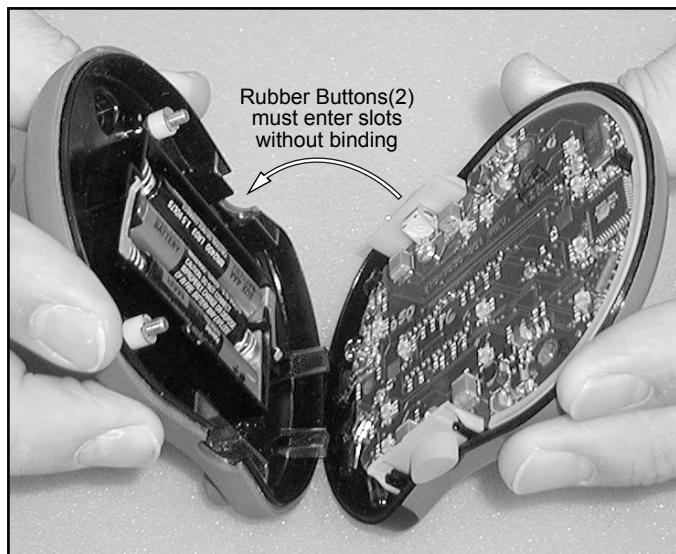


Figure 4-1. Remote Control Battery Replacement

LASER MAINTENANCE

Calibration verification must be performed at least every twelve months to verify that the laser output is within tolerance and calibration is not required. It is recommended to call Alcon Technical Services before conducting the calibration verification procedure.

CAUTION

Serious damage to the instrument may occur if these procedures are not performed by qualified personnel.

Special Tools

- Computer with browser software (MicroSoft* Internet Explorer or equivalent); TFTP file transfer program, or equivalent.
- Custom service ethernet cable (Alcon p/n 023-100)
- Power Meter, Thermopile type (Coherent FieldMaster w/ LM-10 head or equivalent)
- Energy Meter (optional) for direct energy measurements (Ophir Nova meter, with 3A-P or PE25-BB head, or equivalent)
- Oscilloscope / Voltmeter (Fluke Scopemeter, or equivalent)
- Laser Safety Goggles (OD4 or above, at 532 nm wavelength)
- Optics cleaning kit, including spectroscopic grade methanol, lens paper, and air blower
- LIO Voltage Load Box (Alcon dwg 995-5620-069)
- Timing Photocell (Alcon dwg 995-5320-038)

Service Computer Connection

A computer with an ethernet connection and browser software (MicroSoft* Internet Explorer or equivalent) is required to calibrate the *Constellation®* laser. The IP / URL addresses and passwords used to establish communication are subject to change. Contact Alcon Technical Services for information on the most current settings.

In some cases it may be necessary to temporarily change the TCP/IP settings and/or proxy/firewall settings on the service computer, and this usually requires administrative access rights.

The ethernet cable used for service computer connection is a custom cable. Contact Alcon Technical Services for more information.

LASER POWER VERIFICATION

WARNING!

Laser light emitted from the fiber and laser head is powerful enough to cause serious eye or skin damage. Maintenance should be performed only by properly trained personnel, following established guidelines for laser safety. The use of protective eye wear is mandatory.

NOTE: Calibrated Power / Exposure Time may be verified by two different test methods:

- 1) Watts X Time method:** Use an oscilloscope to measure exposure time, and power meter to measure output power, and perform the multiplication to enter value in the energy matrix on the data sheet.
- 2) Energy method:** If an appropriate energy-meter is available, enter “N/A” for the exposure time and power fields on the data sheet, and use the energy-meter to measure and record values directly into the energy matrix.

1 Exposure Time Verification

- 1.1 Connect a test fiber or endoprobe to the system and direct the distal output into the photo cell connected to an oscilloscope.
- 1.2 Adjust the distance between the endoprobe and photo cell to obtain a beam size of 2 mm or more on the photo cell. Use aiming beam to determine spot size on the photo cell.
- 1.3 Set the exposure time to 0.01 s and treatment beam power to minimum, then select READY mode.
- 1.4 Fire the laser and record the exposure time as determined from the oscilloscope.
- 1.5 Repeat steps 1.3 and 1.4 for each time value listed in Table 4-1.

2 Endoprobe Power Verification

- 2.1 Direct the endoprobe distal output beam into the wattmeter cell connected to a wattmeter.
- 2.2 Set the exposure time to CW.
- 2.3 Set the treatment power to 0.10 W then press the Standby/Ready key.
- 2.4 Fire the laser and record the power reading as determined from the Wattmeter.
- 2.5 Repeat steps 2.3 and 2.4 for each value listed in the Endoprobe section of Table 4-1.

3 LIO Power Verification

- 3.1 Direct the LIO distal output beam into the wattmeter cell.
- 3.2 Set the exposure time to CW.

- 3.3 Set the treatment power to 0.10 W then press the Standby/Ready key.
- 3.4 Fire the laser and record the power reading as determined from the Wattmeter.
- 3.5 Repeat steps 3.3 and 3.4 for each value listed in the LIO section of Table 4-1.

4 Energy Matrix Completion

- 4.1 Complete the matrix in Table 4-1 by multiplying actual power by actual exposure time and recording the result, as shown in the example below.

| | | |
|--------------------------------|---------------------|--|
| Measured power entered here | 0.01 S | Measured exposure time entered here |
| 0.50 W | <u>0.51</u> | <u>0.011</u> |
| | <u>0.00561</u> | Product of power x time entered here and compared to tolerance in brackets. |
| | (0.00425 - 0.00575) | |

- 4.2 Ensure that all calculated results are within the values listed in each matrix cell. The listed values are $\pm 15\%$ of the set energy.
 - If all calculated energy values are within the specified limits, the system calibration is OK.
 - If any of the calculated energy results are not within the specified limits, the terminal efficiencies will need to be adjusted. Perform the "Setting the Calibration Factor (Terminal Efficiencies)" procedure following Table 4-1, or call Alcon Technical Services.

5 Aiming Beam Calibration

- 5.1 With the unit off, connect the service ethernet cable between the *Constellation®* console "Tethered Laser" connector on the rear panel, and service computer then turn the system ON. Allow two minutes for the Laser Module to initialize.
- 5.2 Type the IP address into the address box, and hit return. When the page loads, enter the password. Click the Output Calibration tab at the top of the screen.
- 5.3 Adjust aiming beam power output for Port 1 as high as possible but less than 950 μ W.
- 5.4 Click "Set Max Value" for Aiming Beam on the computer.
- 5.5 Repeat for Port 2.

6 LIO Illumination Calibration

- 6.1 Connect the LIO Voltage Load Box to the front panel LIO Illumination port, and connect the scopemeter/DVM across the resistor to read the voltage.
- 6.2 Adjust LIO Illumination knob to obtain 6.3V +/- 0.3V.
- 6.3 Click "Set Max Value" for LIO Illumination on the computer.

Table 4-1 **Laser Energy Matrix for Calibration Verification**

| | | Exposure Time > | 0.01 S |
|-----------|--------|-----------------|-------------------|
| Power | | V | |
| ENDOPROBE | 0.10 W | _____ | (0.0085 - 0.0115) |
| | 0.30 W | _____ | (0.0255 - 0.0345) |
| | 0.70 W | _____ | (0.0595 - 0.0805) |
| LIO | 0.10 W | _____ | (0.0085 - 0.0115) |
| | 0.30 W | _____ | (0.0255 - 0.0345) |
| | 0.70 W | _____ | (0.0595 - 0.0805) |

SETTING THE CALIBRATION FACTOR (TERMINAL EFFICIENCIES)

If unable to successfully complete the Energy Matrix table, use the following procedure to adjust the Calibration Factor, and retest.

- 1 With the unit off, connect the service ethernet cable between the *Constellation®* console “Tethered Laser” connector on the rear panel and service computer, then turn system ON. Allow two minutes for the laser module to initialize.
- 2 Turn the computer ON and start the browser program. Type the IP address into the address box, and press return. When the page loads, enter the password.
- 3 On the Internal Calibration screen, enter 100% for Calibration Factor for Endo and LIO, and click Save for each. Restart the system when complete.
- 4 Direct the distal output beam of the selected device into the wattmeter cell. Set power to 1.0 watt on the console, exposure time to CW, and select READY mode.
- 5 Fire the laser and record the power reading as determined from the wattmeter. Divide the reading, in milliwatts, by 10 to determine the new value for Calibration Factor for that device.
Example: 895 milliwatts recorded power = 89.5% Calibration Factor
- 6 Using the service computer, return to the Internal Calibration screen, enter the new value in the Calibration Factor window for the respective device, and click the SAVE button. Restart the system when complete.
- 7 Repeat as needed to bring all values within compliance to complete the Energy Matrix in Table 4-1, for each delivery device. If unable to successfully complete the matrix, perform the Laser Calibration procedure on the next page.

LASER CALIBRATION

WARNING!

Laser light emitted from the fiber and laser head is powerful enough to cause serious eye or skin damage. Maintenance should be performed only by properly trained personnel, following established guidelines for laser safety. The use of protective eye wear is mandatory.

- 1 With the unit off, connect the service ethernet cable between the *Constellation®* console “Tethered Laser” connector on the rear panel and service computer, then turn system ON. Allow two minutes for the laser module to initialize.

Note: IP / URL addresses and passwords are subject to change. Contact your local Alcon representative for information on most current settings.

- 2 Type the IP address into the address box, and press return. When the page loads, enter the password.

3 Photomonitors Calibration

Pmon 1 Low-Power Calibration -

- 3.1 Select Port 1 on the console.
- 3.2 Press “Output Calibration” tab on computer.
- 3.3 Set laser in CONTINUOUS mode on the console.
- 3.4 Set POWER to 100 mw on the console.
- 3.5 Select READY mode on the console.
- 3.6 Press “Start Pmon1 Calibration” on the computer.
- 3.7 Fire the laser and measure output power directly from Port 1.
- 3.8 Input 0.10 W into the Low Power Display field.
- 3.9 Input the power, as previously measured, into the Actual Low Power Field, and press Save.
- 3.10 Repeat the Pmon 1 Low-Power Calibration as needed (two or three times) to bring Displayed/Actual tracking as close as possible.

Pmon 1 High-Power Calibration -

- 3.11 Set laser in CONTINUOUS mode on the console.
- 3.12 Set POWER to 1 Watt on the console.
- 3.13 Select READY mode on the console.
- 3.14 Press “Start Pmon1 Calibration” on the computer.
- 3.15 Fire the laser and measure output power directly from Port 1.
- 3.16 Input 1.0 Watt into the High Power Display field.

- 3.17 Input the power, as previously measured, into the Actual High Power Field, and press Save.
- 3.18 Repeat the Pmon 1 High-Power Calibration as needed (two or three times) to bring Displayed/Actual tracking as close as possible.
- 3.19 Repeat steps 3.1 through 3.20 for Low/High Power Calibration for Pmon 2.
- 3.20 Repeat Laser Power Verification and Setting the Calibration Factor as required to successfully complete the Energy Matrix for each delivery device, then continue to step 4.

4 Exposure Time Calibration

- 4.1 Use the test setup described in Exposure Time Verification and set the output power to 30 mW, exposure time to 10 mS, Single Shot mode.
- 4.2 Fire the laser and determine the actual values for exposure and interpulse times, as measured on the oscilloscope. Enter and save the correction value, on the Internal Calibration screen, to bring the actual time value as close as possible to the displayed value.
- 4.3 Select Repeat mode and set the interpulse time to 30 mS.
- 4.4 Fire the laser and determine the actual value for interpulse time as measured on the oscilloscope. Enter and save the correction value on the internal calibration screen to bring the actual time value as close as possible to the displayed value.

SECTION FIVE TROUBLESHOOTING

System Messages

The system communicates information to the user through the display of System Messages which are displayed and described to the user as Faults, Errors, Advisories or System Information. These terms are used to classify the level of response required to ensure fail-safe operation of the system. The presentation of a System Message alone does not indicate that a malfunction has occurred. System Messages typically occur when the system detects a condition that is not met but is required for the system to continue. System Messages and associated actions are intended functions presented as a precursor to mitigate an unanticipated condition.

System Messages are priority based, with Fault Messages being the highest priority, followed by Error Messages, Advisory Messages, and System Information. Each type of message is color coded as follows:

- Fault - Red
- Error - Yellow
- Advisory - Green
- Information - Blue

Each message also has a number associated with it that indicates the submodule that prompted the message. The number range for each submodule in the system is assigned as follows:

- Host Submodule - 1000 to 1999
- Supervisor Submodule - 2000 to 2999
- Fluidics Submodule - 3000 to 3999
- US/Diathermy Submodule - 4000 to 4999
- Table Top Illuminator Submodule - 5000 to 5999
- Pneumatics Submodule - 6000 to 6999
- Auxillary Illuminator Submodule - 7000 to 7999
- Laser Submodule - 8000 to 8999

When an Advisory or Information message is displayed that is related to a setup issue, it may be helpful to access the Video or Wizard Help for assistance in solving the issue. These help aids are available in any of the setup screens by pressing the Help button.

The Event Log (shown in Figure 5-10) displays a list of the system messages that have occurred on the system. It is recommended to view the Event Log for details of a system message prior to calling your local Alcon representative for assistance.

For additional assistance in determining what action to take in the event a system message is displayed, refer to the Troubleshooting Guide in Figure 5-11 .

System Fault Messages

System Fault messages are displayed full screen as shown in Figure 5-1. These messages are displayed when the host or supervisory modules detect a condition that is not met and requires the system to shutdown in a safe state. The system performs the following actions when a fault condition is detected:

- Place sub-systems into a safe state.
- A Fault message popup window is displayed.
- A fault tone is activated.
- Ignores any input from all the keys and the footswitch.
- The user must cycle power to reset the system.



Figure 5-1 System Fault Display Screen

System Error Messages

System Error messages are displayed in a popup window as shown in Figure 5-2. These messages are displayed when the system detects a condition that is not met and requires partial elements of the system to shutdown in a safe state. The partial shutdown cannot be reversed until the next power cycle. The system performs the following actions when an error is detected.

- Surgical modes related to the condition are disabled.
- An Error message popup window is displayed. If the condition does not affect the current active modes, they will remain activated, but the message will still be displayed. The message is removed when the operator presses a button on the System Error to acknowledge the message.
- An error tone is activated.
- User Interface controls associated with unavailable modes will be displayed/grayed. If an unavailable mode is interacted with, the system message will again be displayed with accompanying error tone.
- Modes that the system has made unavailable in order to mitigate risk will not again be made available until the system power is cycled.



Figure 5-2 System Error Popup Window

System Advisory Messages

System Advisory messages are displayed in a popup window as shown in Figure 5-3. Advisory messages are displayed when the system detects that a minor condition is not being met, typically a situation that can be corrected by the user. When an advisory is detected, the following actions occur:

- Surgical Modes related to the advisory are not available.
- An Advisory message popup window is displayed to inform the user of a condition that requires corrective action. The popup is removed if the condition is corrected or if the operator presses a button on the Advisory to acknowledge the advisory.
- Certain advisory messages that only present a single user response button may also be configured to automatically fade away. Fading Advisory messages shall be displayed for 20 seconds after which, in the absence of a user response, will fade away.
- An advisory tone is activated.

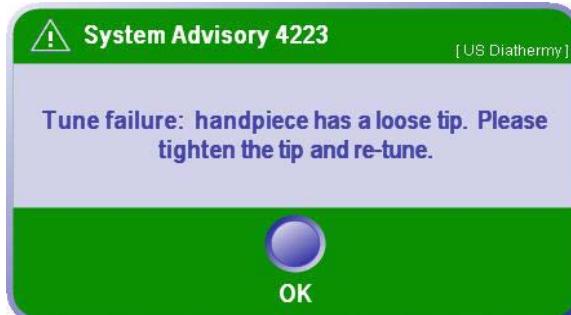


Figure 5-3 System Advisory Popup Window

System Information Messages

Information messages are displayed in a popup window as shown in Figure 5-4. Information messages are displayed to advise the user of the current system state based upon current user interaction. When an information condition is detected the following actions occur:

- An Information message popup window is displayed. The popup is displayed until the condition no longer exists or applies to the current operating mode, or the operator presses a button on the System Info to acknowledge the message.
- Certain informational messages that only present a single user response button may also be configured to automatically fade away. Fading informational messages shall be displayed for 20 seconds after which, in the absence of a user response, will fade away.
- An information tone is activated.

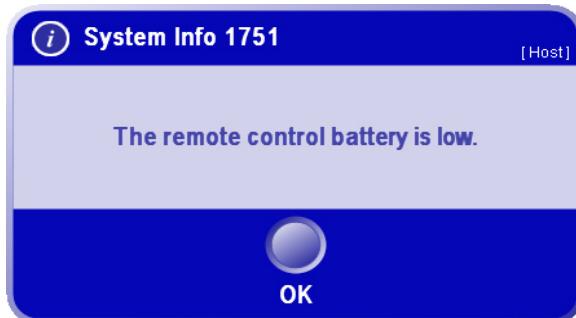


Figure 5-4 System Information Popup Window

Power Lost/Recovery

If the system experiences a loss of power, all surgical functions are stopped and the "Power Lost" message shown in Figure 5-5 is displayed. If power is restored within 1 minute, the system displays the "Power Recovered" message and the system will be restored to the doctor and settings in use at the time of power loss. Accumulated metrics and calibration state are not restored. In order to resume a procedure after a loss of power, the cassette must be reprimed, and handpieces/probes must be recalibrated/reprimed.



Figure 5-5 Power Lost and Power Recovered Screens

RECOVERY FROM A FAULT SCREEN OR UNEXPECTED SHUT DOWN

- 1 Stabilize eye. Leave infusion canula in, remove other instruments (i.e. vit probe/ illuminator) and plug trocar canula's/sclerotomies.

Turn system ON (press the Standby Switch) or if a Fault Screen is displayed, select “Quick Start” (see Figure 5-6).



Figure 5-6 Standby Switch Location and Quick Start Button on Fault Screen

- 2 Immediately clamp smaller infusion canula tubing with hemostats. (See Figure 5-7). Infusion pressure will be off when Setup Screen is displayed.

NOTE: The yellow stopcock is optional and may not be part of setup.

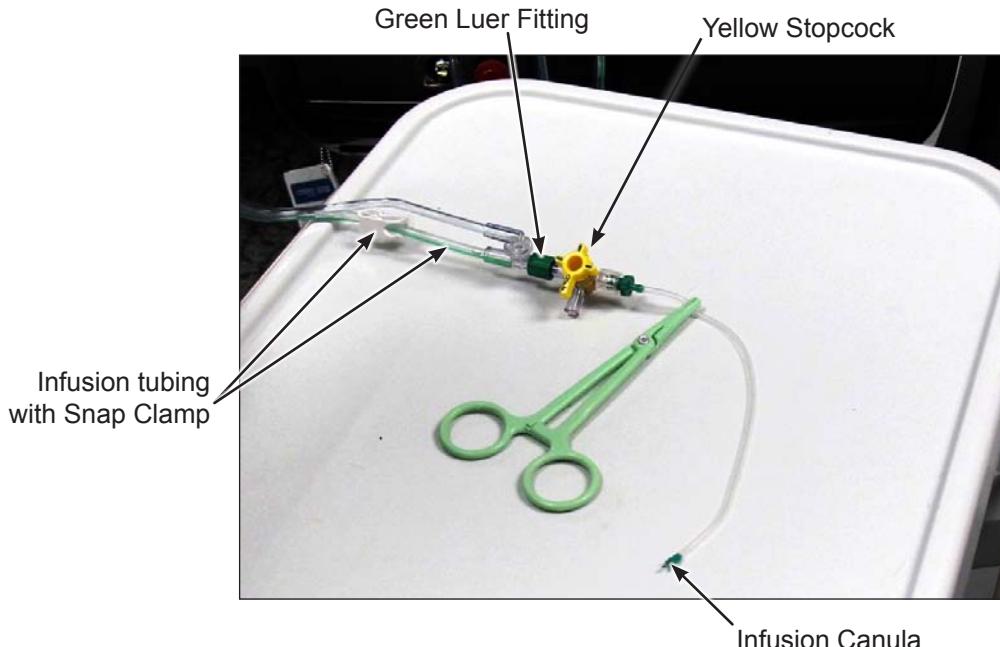


Figure 5-7 Clamped Infusion Canula Tubing (Stopcock optional)

NOTE: DO NOT select Doctor and Procedure until prime is complete. IOP Control, if being used, will NOT be available. Machine will default to pressurized infusion.

- 3 Disconnect green luer fitting from infusion tubing or stopcock.
- 4 Place green striped infusion tubing with snap clamp in a sterile cup as shown in Figure 5-8.

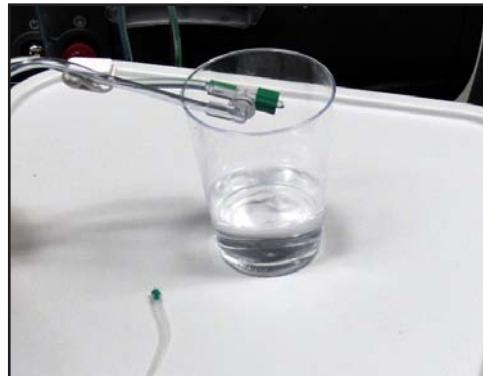


Figure 5-8 Infusion Tubing in Sterile Cup

- 5 Ensure snap clamp is open.
- 6 When Setup Screen is displayed, select the following
 - PROBE “Skip Prime” (see Figure 5-9)
 - Handpiece “None”

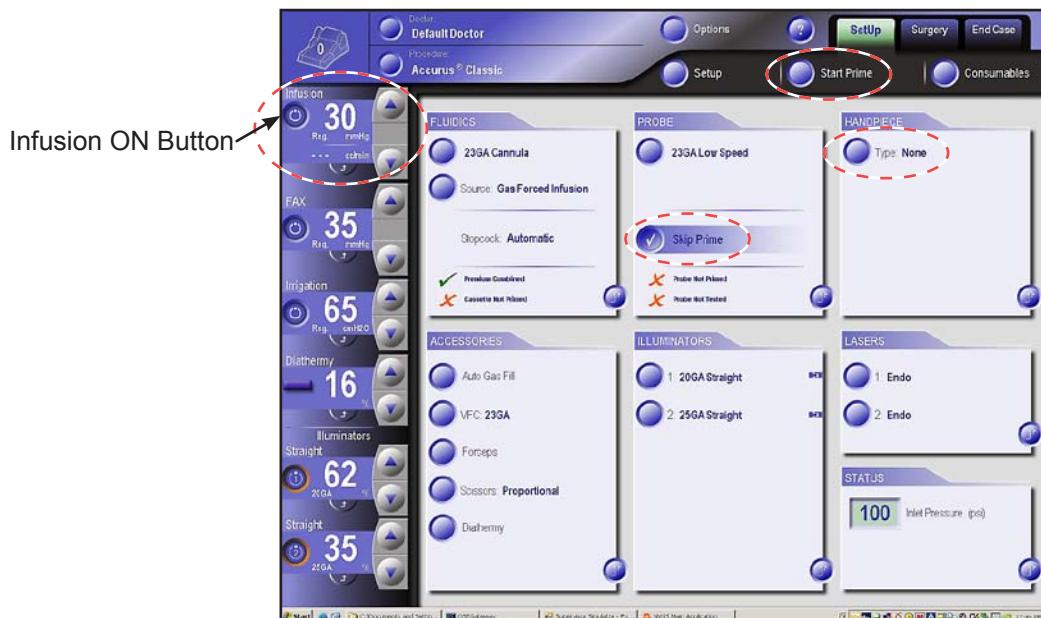


Figure 5-9 Setup Screen Selections

- 7 Select “Start Prime”. **NOTE: Priming will take about 1 minute to complete.**
- 8 Press Infusion ON button and clear any bubbles.
- 9 Close the snap clamp.
- 10 Reconnect the green luer fitting.
- 11 Open snap clamp and remove hemostats from the smaller infusion tubing.
- 12 Select Doctor and Procedure, then continue the case.

Event Log

Figure 5-10 shows the Event Log where system messages are displayed that have occurred during the previous seven days. The list can be filtered to display a specific type of message by pressing the associated button on the right side of the screen.

To view the Event Log:

1. Press Options from the Menu bar.
2. Under the Info tab press "Event Log." The default view is displayed showing a list of all faults, errors, advisories, and information messages. Pressing the associated button will hide that type of message on the list. If the list goes beyond the viewable area, a scroll bar is provided to move through the list.
3. For an expanded view of a specific message, select the message on the list, then press View Details. A pop up appears with a description of the message and the date and time it occurred.
4. Press Close to go back to the previous screen.

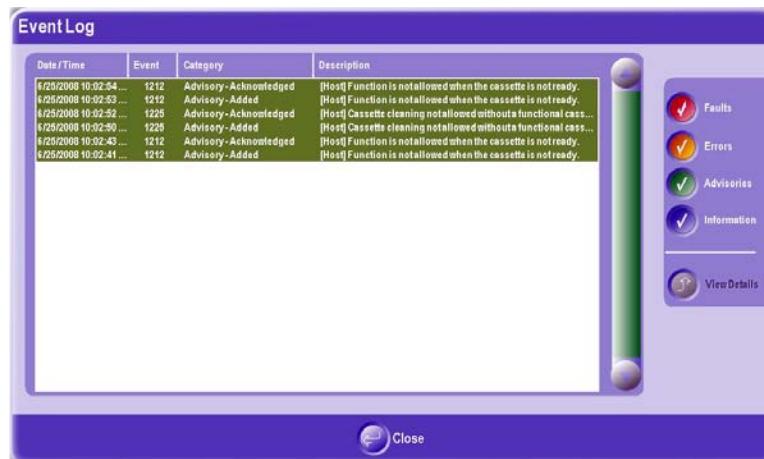


Figure 5-10 The Event Log

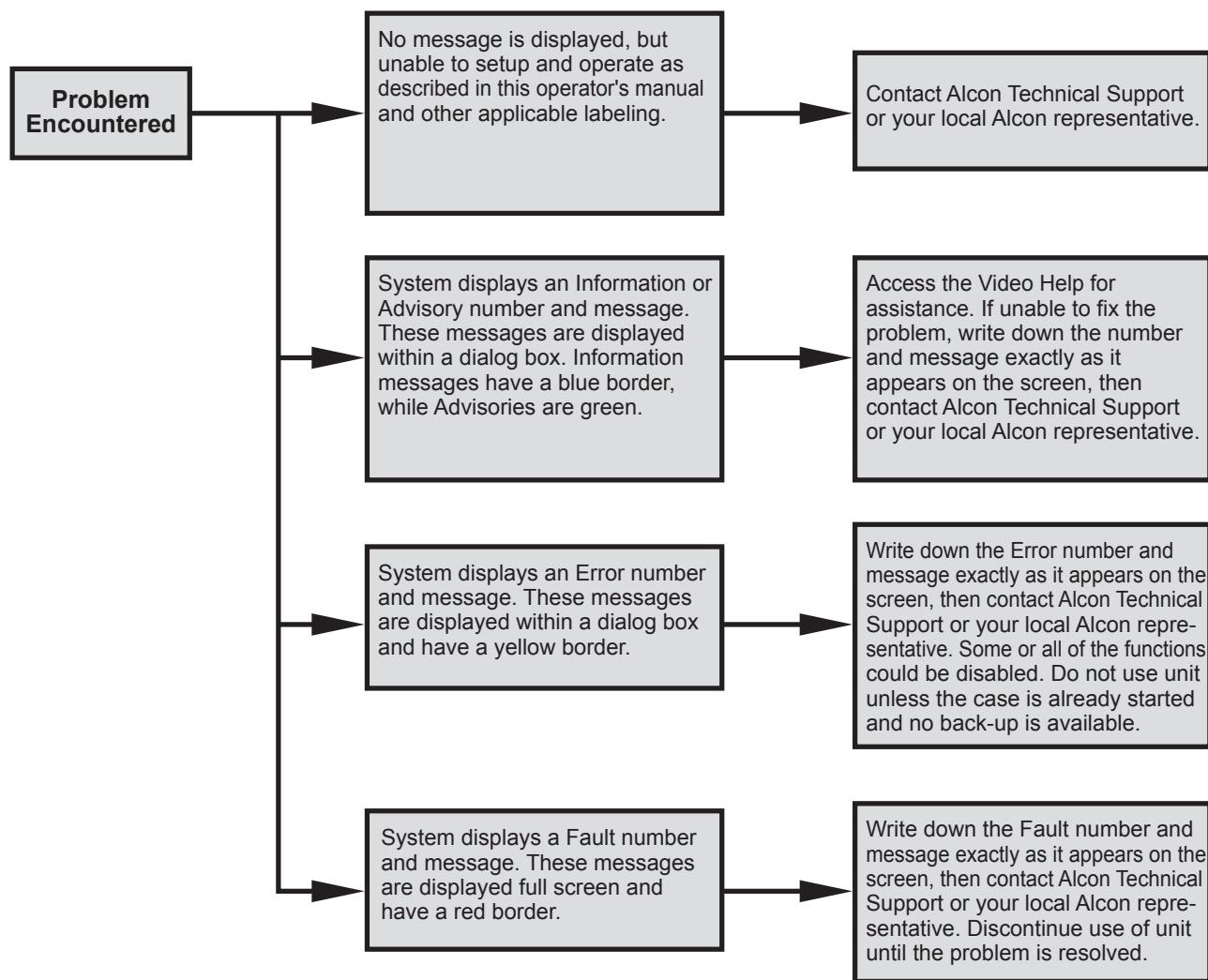


Figure 5-11 Troubleshooting Guide

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SECTION SIX

ACCESSORIES AND PARTS

In this section of the *Constellation®* Vision System Operator's Manual is a list of Alcon-approved accessories and replacement items. **Use of non-approved accessories is not permitted.**

Please contact the Alcon Sales Department for in-service information prior to initial use of handpieces, accessories, or packs. For additional information, please contact the Alcon Sales Department.

| | |
|--------------------------|----------------------------|
| Phone: | Write: |
| (800) 862-5266 or | Alcon, Inc. |
| (817) 293-0450 | 6201 South Freeway |
| Ask for Customer Service | Fort Worth, TX. 76134-2099 |

INTERNATIONAL: Please contact your local Alcon Sales Office.

The *Constellation®* Vision System is designed around the Table Top and the accessories listed in Table 6-1 can be added for expanded functionality. The Table Top can operate as a standalone unit, and is also the primary user interface that operates and controls the add-on accessories. The laser module, auxiliary illuminator, and the tray arm assembly attach to the Base therefore the Base must be installed in order to use these accessories.

Table 6-1. General Accessories

| DESCRIPTION | SUPPLIED BY | CATALOG NUMBER/SUPPLIER |
|---|-------------|--|
| Table Top* | Alcon | 8065751150 8065751536 (China) 8065751817 (Japan) |
| Base Unit* | Alcon | 8065751451 |
| Laser Module Kit* | Alcon | 8065751450 |
| Auxiliary Illuminator* | Alcon | 8065751452 |
| TRAY ARM ASSEMBLY* (all three items required): • Tray Arm • Ballast • Support Column | Alcon | 8065751539 8065751540 8065751541 |
| <i>Constellation®</i> Remote | Alcon | 8065750968 |
| <i>Constellation®</i> Footswitch | Alcon | 8065750977 |
| <i>Constellation®</i> Pneumatic Pressure Hose | Alcon | 8065751694 |
| Monolith Dust Cover | Alcon | 8065751507 |
| Table Dust Cover | Alcon | 8065751508 |
| Laser Footswitch | Alcon | 562-1360-501 |
| Laser Room Interlock | Alcon | 562-1362-501 |
| <i>PurePoint®</i> LIO | Alcon | 8065751050 |
| <i>PurePoint®</i> LIO RFID | Alcon | 562-1331-001 |
| MMC Data Card | Customer | Any SD data card up to 2 GB |
| Printer(s)*: • Network printer with Postscript or PCL (5/6) capabilities. • Universal Plug-n-Play (UPNP) capable printer. | Customer | -- |
| Wireless Router* | Customer | Linksys Wireless G; 2.4 GHz |
| Video Recorder | Customer | Sony DVO-1000MD |
| Video Recorder - High Definition | Customer | Sony HVO-1000HD |

* Alcon installation required

NOTE: Refer to the Directions For Use (DFU) included with each accessory kit/consumable pack for detailed instructions on how to setup that accessory.

Table 6-2. General Consumables

| DESCRIPTION | CATALOG NUMBER |
|--|----------------|
| Remote Control Transfer Pouch | 20000TP |
| Constellation® Standalone Drain Bags | 8065751162 |
| Constellation® Tray Arm Cover | 8065751163 |
| Infusion Tubing Set with Auto Infusion Valve | 8065750914 |
| Infusion tube Set with Manual Stopcock | 8065751816 |
| Auxiliary Aspiration Tubing | 8065750917 |
| Irrigation/Aspiration Tubing Set | 8065750918 |
| GFI Administration Tubing Set | 8065750920 |

Table 6-3. Laser Accessories and Consumables

| DESCRIPTION | CATALOG NUMBER |
|---|----------------|
| PurePoint® Laser System | 8065750597 |
| Filter, Microscope Wild | 8065-5002-01 |
| Front Actuated Filter, Microscope | 8065750448 |
| PurePoint® LIO | 8065751050 |
| Passive Dr. Filter | 8065751051 |
| 25 GA Straight Laser Probe with RFID | 8065750978 |
| 20 GA Curved Laser Probe - CHANG Aspirating with RFID | 8065750979 |
| 20 GA Straight Laser Probe - CHANG Aspirating with RFID | 8065750980 |
| 20 GA Straight Laser Probe - CHANG Aspirating Soft Tip with RFID | 8065750981 |
| 20 GA Curved Illuminated Laser Probe with RFID-SMA/STD ACMI | 8065750982 |
| 20 GA Straight Illuminated Laser Probe with RFID-SMA/STD ACMI | 8065750983 |
| 20 GA Curved Illuminated Laser Probe with RFID-SMA/RFID-ACMI | 8065750985 |
| 20 GA Straight Illuminated Laser Probe with RFID-SMA/RFID-ACMI | 8065750986 |
| 20 GA Curved Laser Probe with RFID | 8065750989 |
| 20 GA Straight Laser Probe with RFID | 8065750990 |
| 23 GA Straight Laser Probe with RFID | 8065750991 |
| 23 GA Flexible Tip Laser Probe | 8065751111 |
| 25 GA Flexible Tip Laser Probe | 8065751112 |
| 23 GA Flexible Tip Laser Probe with RFID | 8065751113 |
| 25 GA Flexible Tip Laser Probe with RFID | 8065751114 |
| 23 GA Illuminated Flexible Curved Laser Probe | 8065751588 |
| 25 GA Illuminated Flexible Curved Laser Probe | 8065751589 |
| 23 GA Illuminated Flexible Curved Laser Probe with RFID-SMA/STD-ACMI | 8065751590 |
| 25 GA Illuminated Flexible Curved Laser Probe with RFID-SMA/STD-ACMI | 8065751591 |
| 23 GA Illuminated Flexible Curved Laser Probe with RFID-SMA/RFID-ACMI | 8065751592 |
| 25 GA Illuminated Flexible Curved Laser Probe with RFID-SMA/RFID-ACMI | 8065751593 |
| 27+™ Flexible Tip Laser Probe | 8065751708 |
| 27+™ Flexible Tip Laser Probe w/ RFID | 8065751709 |

Table 6-4. Posterior Segment Accessories

| DESCRIPTION | CATALOG NUMBER |
|---|----------------|
| <i>UltraVit® Probes</i> | |
| Constellation® 20 GA UltraVit® Vitrectomy Probe, 5000 CPM | 8065750948 |
| Constellation® 23 GA UltraVit® Vitrectomy Probe, 5000 CPM | 8065750949 |
| Constellation® 25 GA UltraVit® Vitrectomy Probe, 5000 CPM | 8065750950 |
| Constellation® 25+™ UltraVit® Vitrectomy Probe, 5000 CPM | 8065751438 |
| Constellation® 23 UltraVit® Vitrectomy Probe, 7500 CPM | 8065751571 |
| Constellation® 25 GA UltraVit® Vitrectomy Probe, 7500 CPM | 8065751569 |
| Constellation® 25+™ GA UltraVit® Vitrectomy Probe, 7500 CPM | 8065751570 |
| 27+™ UltraVit® 7500 CPM Vit Probe | 8065751700 |
| <i>Endoilluminators with RFID</i> | |
| 20 GA Straight Endoilluminator w/ RFID | 8065750971 |
| 23 GA Straight Endoilluminator w/ RFID | 8065750972 |
| 20 GA Shielded Bullet Endoilluminator w/ RFID | 8065750973 |
| 20 GA Bullet Endoilluminator w/ RFID | 8065750974 |
| 20 GA Sapphire Wide Angle Endoilluminator w/ RFID | 8065750975 |
| 25 GA Straight Endoilluminator w/ RFID | 8065750976 |
| 20 GA Bare End Endoilluminator | 8065750998 |
| 20 GA Ryan Pik Endoilluminator | 8065751000 |
| 20 GA End Irrigating Endoilluminator | 8065751001 |
| 20 GA Illuminated Mem Pik | 8065751002 |
| 20 GA Shielded Bullet Endoilluminator w/ Pik | 8065751003 |
| 23 GA Sapphire Wide Angle Endoilluminator w/ RFID | 8065751184 |
| 25 GA Sapphire Wide Angle Endoilluminator w/ RFID | 8065751185 |
| 25+™ Straight Endoilluminator w/RFID | 8065751441 |
| 25+™ Sapphire Wide Angle Endoilluminator w/ RFID | 8065751486 |
| 25 GA Illuminated Mem Pik | 8065751572 |
| 23 GA Chandelier | 8065751573 |
| 23 GA Illuminated Mem Pik | 8065751576 |
| 25 GA Chandelier | 8065751577 |
| 27+™ Endoilluminator | 8065751701 |
| <i>Endoilluminators</i> | |
| Wide Angle Diffusion Light Pipe (Product of Grieshaber) | 630.45 |
| <i>Infusion and Extrusion Accessories</i> | |
| 20 GA Self Retaining Infusion Cannula, 4.0 mm | 8065750580 |
| 23 GA Infusion Cannula | 8065750841 |
| 25 GA Infusion Cannula | 8065751459 |
| 20 GA Self-Retaining Infusion Cannula w/Tray | 8065752148 |
| 23 GA Infusion Cannula w/Tray | 8065752149 |
| 23 GA Sutured Infusion Cannula, 4mm w/Tray | 8065752150 |
| 25 GA Infusion Cannula w/Tray | 8065752151 |
| 27+™ Infusion Cannula w/Tray | 8065752173 |
| 20 GA Straight. Blunt TIP Needle | 800-26A |
| 20 GA Tapered Blunt Tip Needle | 800-26B |
| 19 GA Straight. Blunt Tip Needle | 800-26C |
| 19 GA Tapered Blunt Tip Needle | 800-26D |
| 19 GA Soft Tip Extrusion Needle | 8065149510 |
| 20 GA Soft Tip Extrusion Needle | 8065149520 |

Table 6-4. Posterior Segment Accessories

| DESCRIPTION | CATALOG NUMBER |
|--|----------------|
| 23 GA Soft Tip Extrusion Needle | 8065149523 |
| 25 GA Soft Tip Needle | 8065149525 |
| 25 GA Small Parts Kit | 8065750404 |
| 25 GA Trocar Plug | 8065750189 |
| 23 GA Small Parts Kit | 8065750842 |
| 23 GA Trocar Plug | 8065750837 |
| 19/20 Gauge Scleral Plugs | 8065807550 |
| 27+™ Valved Entry System 3 ea | 8065751697 |
| 23GA 6 mm Cannula 1 ea | 8065751444 |
| 23GA 6 mm Cannula 3 ea | 8065751445 |
| 23GA Enhanced Entry System 1 ea | 8065751446 |
| 25GA 6 mm Cannula 1 ea | 8065751780 |
| 25GA 6 mm Cannula 3 ea | 8065751781 |
| 23GA Enhanced Entry System 3 ea | 8065751447 |
| 25GA Enhanced Entry System 1 ea | 8065751448 |
| 25GA Enhanced Entry System 3 ea | 8065751449 |
| 23GA Valved Entry System 1 ea | 8065751585 |
| 25GA Valved Entry System 1 ea | 8065751586 |
| 23GA Valved Entry System 3 ea | 8065751657 |
| 25GA Valved Entry System 3 ea | 8065751658 |
| Lens Fragmentation | |
| Constellation® Fragmentation Handpiece | 8065750888 |
| 20 GA Fragmentation Pack | 8065750958 |
| Diathermy | |
| 20/23 Ga Tapered Bipolar Brush | 8065807901 |
| 18 Ga Straight Brush | 8065804001 |
| 18 Ga Straight Brush with Cord | 8065804101 |
| 25 Ga Diathermy Probe | 8065751562 |
| Diathermy Probe DSP, 25Ga | 339.21 |
| 27+™ Diathermy Probe, DSP | 339.31 |
| Auto Gas Fill | |
| Auto Gas Fill Pack | 8065751014 |
| C ₃ F ₈ 450 Gram Cylinder | 8065797104 |
| SF ₆ 450 Gram Cylinder | 8065797004 |
| C ₃ F ₈ 125 Gram Cylinder | 8065797105 |
| SF ₆ 125 Gram Cylinder | 8065797005 |
| Pneumatic Handpiece and Accessories | |
| Constellation® Pneumatic Handpiece (Product of Grieshaber) | 725.01 |
| Constellation® Pneumatic Handpiece DSP | 725.03 |
| Posterior Standalone Accessories | |
| Constellation® Viscous Fluid Control (VFC) Pack | 8065750957 |

Table 6-5. Anterior Segment Accessories

| DESCRIPTION | CATALOG NUMBER |
|---|----------------|
| U/S Handpiece | |
| <i>Infiniti</i> ® Ultrasound Handpiece | 8065750121 |
| <i>Infiniti</i> ® OZi® Handpiece | 8065750469 |
| U/S Tips | |
| 30° KELMAN®, 1.1 mm | 30KT |
| 30° KELMAN®, 0.9 mm | 30KTS |
| 30° Round, 1.1 mm | 30RT |
| 30° Round, 0.9 mm | 30RTS |
| 45° KELMAN®, 1.1 mm | 45KT |
| 45° KELMAN®, 0.9 mm | 45KTS |
| 45° Round, 1.1 mm | 45RT |
| 45° Round, 0.9 mm | 45RTS |
| 30° Round, 1.1 mm ABS | 8065740792 |
| 45° Round, 1.1 mm ABS | 8065740793 |
| 30° KELMAN®, 1.1 mm ABS | 8065740794 |
| 45° KELMAN®, 1.1 mm ABS | 8065740795 |
| 30° Round, 1.1 mm Flared ABS | 8065740806 |
| 45° Round, 1.1 mm Flared ABS | 8065740807 |
| 30° KELMAN®, 1.1 mm Flared ABS | 8065740808 |
| 45° KELMAN®, 1.1 mm Flared ABS | 8065740809 |
| 30° Round, 0.9 mm MicroTip Flared ABS | 8065740837 |
| 45° Round, 0.9 mm MicroTip Flared ABS | 8065740838 |
| 30° KELMAN®, 0.9 mm MicroTip Flared ABS | 8065740839 |
| 45° KELMAN®, 0.9 mm MicroTip Flared ABS | 8065740840 |
| 30° Akahoshi, 1.1mm Flared ABS | 8065750186 |
| 30° Round, 0.9 mm Tapered ABS | 8065750261 |
| 45° Round, 0.9 mm Tapered ABS | 8065750262 |
| 30° KELMAN®, 0.9 mm Tapered ABS | 8065750263 |
| 45° KELMAN®, 0.9 mm Tapered ABS | 8065750264 |
| 30° KELMAN®, 0.9 mm Mini-Flared ABS | 8065750852 |
| 45° KELMAN®, 0.9 mm Mini-Flared ABS | 8065750853 |
| 30° OZi® - 12, 0.9 mm Mini-Flared ABS | 8065751176 |
| 45° OZi® - 12, 0.9 mm Mini-Flared ABS | 8065751177 |
| 30° Reverse OZi® - 12, 0.9 mm Mini-Flared ABS | 8065751178 |
| 30° Reverse OZi® - 12, 1.1 mm Mini-Flared ABS | 8065751179 |
| 30° Round, 0.9 mm ABS | 8065790020 |
| 45° Round, 0.9 mm ABS | 8065790021 |
| 30° KELMAN®, 0.9 mm ABS | 8065790022 |
| 45° KELMAN®, 0.9 mm ABS | 8065790023 |
| Irrigation Sleeves/Small Parts Kits | |
| 0.9 mm MICROSMOOTH® High Infusion Sleeve Small Parts Kit | 8065740842 |
| 1.1 mm MICROSMOOTH® High Infusion Sleeve Small Parts Kit, | 8065740872 |
| 0.9 mm MICROSMOOTH® Small Parts Kit, | 8065750159 |
| 1.1 mm MICROSMOOTH® Small Parts Kit, | 8065750160 |
| 0.9 mm MICROSMOOTH® Ultra Sleeves Small Parts Kit | 8065750517 |
| 1.1 mm MICROSMOOTH® Ultra Sleeves Small Parts Kit | 8065750518 |

Table 6-5. Anterior Segment Accessories

| DESCRIPTION | CATALOG NUMBER |
|---|-----------------|
| 1.1 mm <i>MICROSMOOTH</i> ® Micro Sleeves Small Parts Kit | 8065750519 |
| I/A Accessories-Reusable | |
| I/A Tip 0.5 mm | 355-1009 |
| I/A Tip 0.2 mm | 355-1010 |
| I/A Tip 0.3 mm Small Bore | 356-1007 |
| I/A Tip 0.3 mm Small Bore Mod | 356-1009 |
| I/A Tip 0.3 mm Bent | 356-1010 |
| I/A Tip 0.3 mm Bent & Sand Blast | 356-1020 |
| I/A Tip .033 OD, .3mm, Intrepid | 8065751012 |
| I/A Tip .033 OD, .3mm Bent, Intrepid | 8065751013 |
| I/A Tip 0.3 mm, Polymer, Straight | 8065751510 |
| I/A Tip 0.3 mm, Polymer, Angled | 8065751511 |
| I/A Tip 0.3 mm, Polymer, Curved | 8065751512 |
| Silicone I/A Tip, Bent | 8065740969 |
| Silicone I/A Tip, Straight | 8065740970 |
| <i>ULTRAFLOW</i> ® Tool/O-rings | 405-184 |
| <i>ULTRAFLOW</i> ® IA Handpiece Comp | 8065814101 |
| <i>ULTRAFLOW</i> ® IA Handpiece Only | 8065814201 |
| <i>ULTRAFLOW</i> ® IA Tip STR | 8065814301 |
| <i>ULTRAFLOW</i> ® IA Tip CRVD | 8065814401 |
| <i>ULTRAFLOW</i> ® IA 45° | 8065814501 |
| <i>ULTRAFLOW</i> ® IA 90° | 8065814601 |
| <i>ULTRAFLOW</i> ® IA 120° | 8065814701 |
| <i>ULTRAFLOW</i> ® CNL STTL | 8065814801 |
| <i>ULTRAFLOW</i> ® Luer | 8065814901 |
| <i>ULTRAFLOW</i> ® SP Straight Tip, 3 mm | 8065817001 |
| <i>ULTRAFLOW</i> ® Tip Protector, Standalone | 8065817002 |
| <i>ULTRAFLOW</i> ® SP 45° Bent Tip, .3 mm | 8065817201 |
| <i>ULTRAFLOW</i> ® SP 90° Bent Tip, .3mm | 8065817301 |
| <i>ULTRAFLOW</i> ® SP Irrigation Only Luer | 8065817501 |
| <i>ULTRAFLOW</i> ® SP Curved Tip, .3mm | 8065817601 |
| Threaded Tip – STTL | 8065817801 |
| <i>ULTRAFLOW</i> ® I/A Box | 8065-A001-01 |
| Replacement O-ring | ULTRA O-RNG RPL |
| Anterior Vitrectomy | |
| <i>Constellation</i> ® 20 GA Anterior Vitrectomy Pack | 8065751020 |
| Anterior Vitrectomy Coaxial Irrigation Sleeve | 8065750352 |
| Anterior Vitrectomy Irrigation Sleeve (Limited Reuse) | 8065801351 |

Table 6-5. Anterior Segment Accessories

| DESCRIPTION | CATALOG NUMBER |
|--|----------------|
| Bipolar Accessories-Single Use | |
| Curved Jewelers/Iris Forceps | 8065129101 |
| Coaptation Forceps | 8065129301 |
| Straight Jewelers/Iris Forceps | 8065129501 |
| 18 GA, Straight Brush | 8065804001 |
| 20 GA, Straight Brush | 8065804201 |
| 18 GA, Curved Brush | 8065804601 |
| 18 GA, Widestroke Brush | 8065806701 |
| 23 GA, Tapered Brush | 8065807901 |
| Bipolar Brush with Cord Su 18 GA Sterile | 8065804101 |
| Bipolar Brush with Cord Su 20 GA Sterile | 8065804301 |
| Bipolar Brush with Cord Su 18 GA Curved Sterile | 8065804701 |
| Disposable Diathermy Cable (Same as Posterior Segment) | 8065129002 |
| Reusables | |
| Nadler Forceps - 4" type coaptation, 0.4 mm tip | 8065127401 |
| 4" Straight Jewelers Forceps, 0.4 mm Tip | 8065127501 |
| 4" Curved Jewelers Forceps, 0.4 mm Tip | 8065127601 |
| 4" Tenzel Forceps, 0.4 mm Tip | 8065127701 |
| 4 3/4" Adson Forceps, 1.0 mm Tip | 8065127801 |
| 3 1/2" Straight Iris Forceps, 0.4 mm Tip | 8065127901 |
| 3 1/2 "Curved Iris Forceps, 0.4 mm Tip | 8065128001 |
| 4 1/4 " Coaptation Forceps, 0.5 mm Tip | 8065128101 |
| 4 1/4" Coaptation Forceps, Extra Fine, 0.4 Mm | 8065128201 |
| Reusable Diathermy Cable | 8065128402 |
| 3 1/2 " Jewelers Curved Forceps, 0.4 mm Tip | 8065128501 |
| 4" Titanium Coaptation Forceps, 0.5 mm Tip | 8065128601 |
| 4 3/4" Straight/Serrations Forceps, 0.4 mm Tip | 8065128801 |

Constellation® Consumables Pack

The *Constellation® Total Plus® Pak* product family consists of three (3) segment-based procedure packs:

- Vitrectomy Packs (Posterior Segment)
- Phaco Packs (Anterior Segment)
- Combined Procedure Packs (Posterior and Anterior Segment).

The procedure packs are an assemblage of accessories (listed in the previous tables) specifically for use with the *Constellation® Vision System*. Contact your local Alcon Representative for available *Constellation®* Procedure Packs.

ALCON PUREPOINT® LASER INDIRECT OPHTHALMOSCOPE (LIO)

Introduction

The *PurePoint®* Laser Indirect Ophthalmoscope (LIO) is an accessory for use exclusively with the Alcon® *PurePoint®* Laser and the *Constellation®* Vision System. The *PurePoint®* LIO is composed of a *Heine** diagnostic headset with integral laser delivery adaptation and an illumination power supply. The treatment laser beam and the aiming beam are both provided by the *PurePoint®* Laser.

The *PurePoint®* LIO is connected to the laser via a fiber optic cable for the treatment and aiming beams, and by electrical cable for illumination. The illumination light is adjustable from approximately 0 to 1000 lux using the illumination control knob on the power supply.

A permanent Doctor Protection Filter protects the surgeon against incidental laser beam reflections. The operator will have a colored** view through the Doctor Protection Filter due to blocking of the 532 nm wavelength (green).



Figure 6-1 The *PurePoint®* Laser Indirect Ophthalmoscope

** Newer Doctor Protection Filters will have less tint than older ones.

WARNINGS!

The head-worn Laser Indirect Ophthalmoscope (LIO) is designed solely for examination and treatment of the eye, particularly the retina.

Use only the illumination power supply provided on the *Constellation® Vision System* or the *PurePoint® Laser System* (in tethered mode). It is specially designed for the *PurePoint® LIO*.

Insure that the selection on the *Constellation® Vision System* display is LIO. It is the responsibility of the operator to verify that the selection is correctly confirmed.

The operator will have a colored** (pink) view through the Doctor Protection Filter due to blocking of the 532 nm wavelength (green).

The operator must be careful to avoid potential secondary reflections; therefore the room used to treat the patient should be approved by a qualified laser safety officer.

All personnel in the treatment room must wear protective eyewear (OD 4 or above at 532 nm) when the system is in Standby, Ready, or Firing modes.

The laser delivery system is an integral part of the LIO and is not designed to be used with an observer. Never use a teaching or observation system in conjunction with the LIO. There is no eye protection provided for the observer.

Before each use of the headset, the operator must check the permanent Doctor Protection Filter for scratches, breaks, or alterations. If there is any doubt, please call Alcon Technical Services, and discontinue use of device.

There are potential hazards when inserting, steeply bending, or improperly handling of the fiber optic cable. Not following the recommendations of the manufacturer may lead to damage to the fiber or delivery system and/or harm to the patient or user.

Since the aiming beam passes down the same delivery system as the treatment beam, it provides a good method of checking the integrity of the delivery system. If the aiming beam spot is not present at the distal end of the delivery system, or its intensity is reduced or it looks diffused, this is a possible indication of a damaged or not properly working delivery system. If there is any doubt, contact Alcon Technical Services.

The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen should be avoided. Some materials - for example cotton wool when saturated with oxygen - may be ignited by the high temperatures produced in normal use of the laser equipment. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. There is also danger of ignition of endogenous gases.

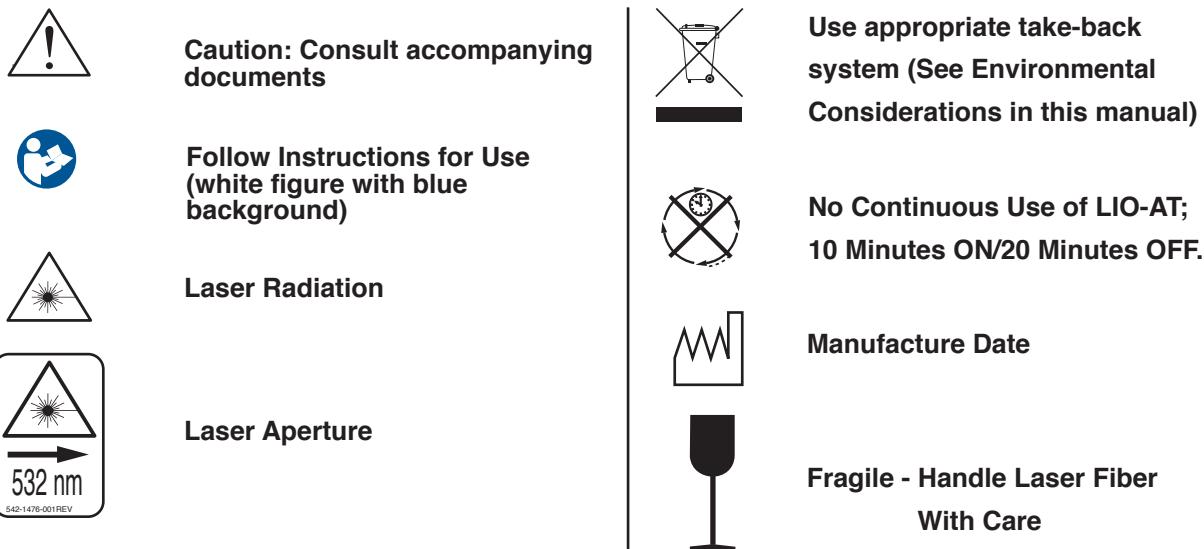
A qualified technician must perform a visual inspection of the following components every twelve months: warning labels, power cords, and fuses. In case of a deficiency, do not use the system; call Alcon Technical Services.

A qualified technician must verify the LIO performance by performing an LIO calibration, power output, and energy matrix test every twelve months to ensure the LIO is operating within specifications. See Section Four of this operator's manual for instructions. If the LIO is not operating within specifications, do not use the system; call Alcon Technical Services.

A qualified technician must check and record ground continuity and both polarities for leakage current every twelve months to ensure they are within the applicable standards (for example: EN60601-1/IEC601-1). If they are above the applicable standards, or 50% above initial measurement, do not use the system; call Alcon Technical Services.

PurePoint® LIO Icons and Labels

The labels and icons shown in Figure 6-2 are found on the *PurePoint® LIO* and are defined as indicated.



NOTE: The LIO may use either of the label examples shown above depending upon the date of manufacture.

Figure 6-2 *PurePoint® LIO Labeling*

Table 6-6 *PurePoint® LIO Technical Specifications*

| CATEGORY | SPECIFICATION | |
|---------------------------|---|--|
| Dimensions | Width: 22.0 cm (8.7 inches) Length: 24.2 cm (9.5 inches) Height: 20.0 cm (7.9 inches) | |
| Headset Weight | 571 g (1.26 lbs.) | |
| Environmental Limitations | Operating: Temperature: $15^{\circ}\text{C} \leq T^{\circ} \leq 35^{\circ}\text{C}$ Relative Humidity: 10% to 90% with no condensation Storage: Temperature: $-40^{\circ}\text{C} \leq T^{\circ} \leq 70^{\circ}\text{C}$ Relative Humidity: 10% to 90% with no condensation | |
| Miscellaneous | <p><i>PurePoint®</i> Laser with <i>PurePoint®</i> LIO complies with CE MDD requirements (CE 0123).</p> <p>Not suitable for use in the presence of flammable anesthetic, oxygen, or nitrous oxide.</p> <p>System not protected against the ingress of water.</p> <p>Class I_b,  IEC 601-1</p> | |

PurePoint® LIO Safety Features

- Labels on the instrument warn the operator about laser dangers.
- The illuminator power knob controls the illumination power supply.
- A protective housing covers the laser source completely and the beam will only exit through the LIO exit window.
- A permanent Doctor Protection Filter on the LIO headset protects the operator from incidental reflections of the laser beam. Prior to using the laser system, ensure that the filter is in good condition and that it has not been damaged, displaced, or moved.
- An emergency switch located on the *Constellation®* Vision System can be used to shut off power to the laser. After using the emergency switch, pull it back to its initial position to restore power and start the instrument.

General System Precautions

All personnel operating laser systems shall follow each of the general safety precautions listed below.

- Never look into the laser beam.
- Restrict laser room access to people whose presence is required and who are familiar with the laser precautions.
- The laser room should be clearly identified with proper warning signs.
- Never direct the laser beam towards an opening in the room's light shielding walls or window or door coverings..
- Never place any reflecting object in the path of the laser beam, or direct the laser beam toward objects that may reflect light (such as surgical instruments).
- Turn the LIO illuminator power knob to OFF when not in use.
- Only authorized personnel thoroughly familiar with the recommendations contained in this manual may operate the LIO. Any use of this laser system beyond the design intentions may result in dangerous exposure to laser radiation.
- Familiarity and understanding the use and application of the Indirect Ophthalmoscope is a prerequisite to using the LIO.

Using the Optics Overband

The pivoting overband allows the laser optics to be pushed up out of the operator's field of view (see Figure 6-3). It is locked in the end position and can only be released by pressing the Overband Adjustment Knob.

To pivot the overband, press the Overband Adjustment Knob with the right hand and pivot the overband into the desired position (up for the "rest" position and down for the "working" position). When the unit is properly adjusted, the overband can be lowered into the same pre-selected working position. Once set, changing the adjustments is required only if another examiner uses the instrument.



Figure 6-3 Adjusting the *PurePoint® LIO Overband*

Observation Optics Adjustment

1. Loosen the Observation Optics Adjustment Knob (see Figure 6-4) so that the observation optics are free to move. The Observation Optics Adjustment Knob can be unscrewed and reversed to the other side for left-handed operators. Remove dust cover protecting delivery window.
2. Place the LIO on your head and adjust the circumference and height using the Circumference and Height Adjustment Knobs so that the headband is firmly positioned but comfortable.
3. For convenience, use clothing clip to attach the fiber/cable assembly to clothing.
4. Move the eyepieces as close as possible to your eyes and look at the light spot at a distance of 30 cm. A small object (such as a pencil) held in front of the eyepieces at 30 cm must be clearly focused.
5. Using the Delivery Mirror Control Knob, adjust the optics so that the light spot is centered vertically in your field of view, then tighten the Observation Optics Adjustment Knob.
6. If the light spot is not centered horizontally, adjust the headband left or right accordingly.
7. Adjust the pupil distance setting by viewing the light spot alternately with the left eye then the right eye, and sliding the eyepieces so that the spot is centered within your field of view.
8. Remove the LIO and look at the scale on the eyepieces to insure that the pupil distance is symmetrical. If not, center the headset and readjust the eyepieces. Correct adjustment of the optics is particularly important when examining small pupils.

Once set, changing the adjustments is required only if another examiner uses the instrument.

Controls for Observation and Illumination

The Aperture Lever (see Figure 6-4) allows you to choose between two different-sized illumination fields. The choice of illumination field size depends mainly on the size of the patient's pupil (the small illumination field is the recommended setting). The positions of the Aperture Lever for large and small illumination fields are marked with large and small black dots, respectively.

The Convergence Control Knob provides synchronized adjustment of both examination and illumination beams to suit the patient's pupil size. Wide convergence and parallax selection allows for maximum stereopsis with large pupils. Narrow convergence and parallax selection allows stereoscopic examination for small pupils. **NOTE: Use the small pupil setting and narrowest convergence angle at the small illumination field size setting; otherwise, clipping (shadow) of the illumination field will occur. The Convergence Control Knob adjustment range is limited in the LIO to 50% of the original Heine* range to accommodate for the laser beam delivery requirements.**

The Delivery Mirror Control Knob can be rotated to move both the illumination beam and the laser beam in the vertical plane.

CAUTION

Do not use the LIO with the illumination power supply set at maximum intensity for more than 10 continuous minutes. The LIO must be allowed to cool down at least 20 minutes between uses. Use as little observation/illumination light as possible and always switch power supply OFF using the illuminator power knob.

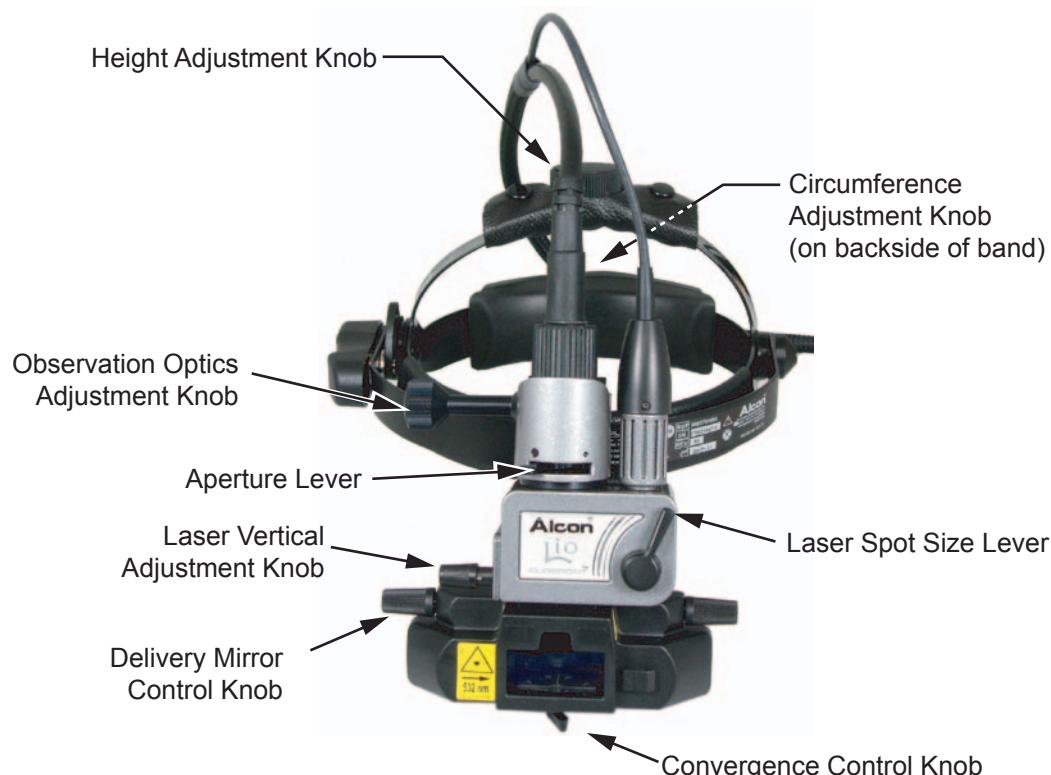


Figure 6-4 PurePoint® LIO Controls and Adjustments

Using the *PurePoint®* LIO for Observation

If the *PurePoint®* LIO is used for illumination purposes only, the laser fiber still needs to be connected to the *PurePoint®* Laser.

1. Turn the illumination power on and adjust the light intensity using the illuminator power knob.

Using the *PurePoint®* LIO for Laser Treatment

Using the system in this mode enables photocoagulation with the LIO.

WARNING!

All the personnel in the room during the operation must wear protective safety eyewear with a minimum optical density OD 4 to filter 532nm radiation.

Before each use of the headset, the operator must examine the permanent Doctor Protection Filter for scratches, breaks, or alterations by looking through the ocular lens. If there is any doubt, discontinue use of device and please call Alcon Technical Service.

NOTE: The *PurePoint®* LIO is shipped with +2 diopter ocular lenses installed. These may be changed with 0 (zero) diopter lenses.

1. If desired, change the ocular lenses by unscrewing the eyecup retainer in the counterclockwise direction, change each lens, and replace the eyecup retainers. Ensure that the new lenses are clean; i.e. no fingerprints or debris. Refer to the *PurePoint®* LIO maintenance section for cleaning instructions.

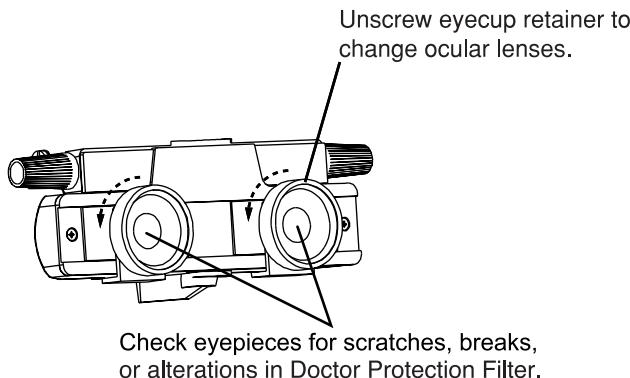


Figure 6-5
Eyecup Retainers and Ocular Lens on the *PurePoint®* LIO

2. Turn the *Constellation®* Vision System console power ON and make the appropriate selections.
3. Select the appropriate illumination field size by toggling the illumination aperture lever to the desired setting.
4. Adjust the illumination intensity using the LIO Intensity up/down buttons.

5. On the touchscreen, set the power below the nominal titration level. If the power parameter is not set below the nominal titration level, the message “Set Power < xxxx mW” will appear on the display.
6. If necessary press the Reset button to reset the shot counter to 0.
You can now adjust exposure time, aiming beam power, and treatment beam power.
7. Select exposure time by pressing the Exposure Time Adjustment arrow buttons.

WARNING!

Verify that all personnel are wearing protective eyewear (OD 4 or above at 532 nm) as soon as the system is in Standby/Ready mode, as well as during treatment.

NOTE: It is not recommended to use exposure times longer than two seconds in CW (Continuous Wave) mode. Depending on the thermal load, the system may shut down prior to the footswitch being released. A message will appear on the display indicating this condition.

8. Select the aiming beam intensity by pressing the Aiming Beam up/down buttons.

WARNING!

Do not attempt treatment if aiming beam is not present. Patient injury may occur.

9. Set the desired treatment power by pressing the Power up/down buttons.
10. Select the laser spot size using the Laser Spot Size lever (see Figure 6-4). The positions of the Laser Spot Size lever for large (approximately 1 mm) and small (approximately 0.5 mm) laser spot sizes are marked with large and small black dots on the right side of the box, respectively. The change of laser spot size from large to small results in approximately four times increase in irradiance within the treatment area, provided that laser power was not adjusted.

It is recommended to adjust laser power each time the Laser Spot Size Control setting is changed. Start with low power and a short duration pulse, then increase until the desired coagulation result is achieved.

WARNING!

If unsure which settings are required, select a low power, short duration, and large laser spot size. Failure to properly adjust delivered energy may lead to patient injury.

11. Press the Ready selection under Laser Mode on the touchscreen. The system will emit a voice confirmation that it has entered Ready mode.

NOTE: The footswitch must be released to proceed to Ready mode. If the footswitch is depressed during power-up or while in Standby mode, “Release footswitch” is displayed. Release footswitch and proceed.

12. Use the Laser Vertical Adjustment knob (see Figure 6-4) on the laser delivery adaptation to aim the laser at the desired location within the illumination field.
13. Press the footswitch when ready to fire. The system will emit a four millisecond beep each time the laser fires. If the footswitch is not pressed within 2 minutes starting from entry into “Ready” mode, the system emits one beep and switches to “Standby” mode.

NOTE: The aiming beam is off during treatment beam exposure, except in repeat mode.

14. Repeat the firing procedure as often as necessary, making adjustments to power output and duration as appropriate to complete the treatment session.
15. When the treatment is completed, release the footswitch and press the Standby button on the touchscreen.

NOTE: The Emergency switch on the front panel must only be used in case of emergency. After using the Emergency switch, return it to its initial position to restore power and start the instrument.

PurePoint® LIO MAINTENANCE

This section contains information for basic care and maintenance of the LIO. If a problem occurs on the instrument, call the Alcon Technical Services department and give details of the breakdown circumstances and effects. From these elements, a technician will evaluate the problem and determine the maintenance requirements.

Checking the LIO Appearance

The condition of the hardware components must be checked periodically to identify any fault which might cause incorrect operation of the system.

- Operation of controls and indicators.
- State of the fibers and connecting cables.
- Check permanent Doctor Protection Filter for damage; i.e., scratches and cracks.

Any damaged hardware must be replaced. Contact your Alcon Technical Service representative.

CAUTION

Care and cleaning operations must be performed with the instrument turned off and power disconnected.

Headset Care and Maintenance

- The eyepieces and the glass in front of the binocular assembly can be cleaned with a soft cloth (dipped in alcohol if necessary).
- The cushions for forehead and nape can be removed for wiping with soapy water.
- The rest of the instrument can be cleaned with a soft cloth dipped in alcohol. Under no circumstances should cleaning fluids be used.

Storage

The *PurePoint® LIO* should be stored either on the headset stand or in its storage case when not in use to prevent inadvertent damage to the headset or cables.

Changing the Illumination Bulb

1. Ensure that the LIO is not connected to the *Constellation® Vision System*.
2. Pull the cord socket away from the bulb connector (see Figure 6-6).
3. Unscrew and remove the bulb connector, then pull the bulb out of the socket.

WARNING!

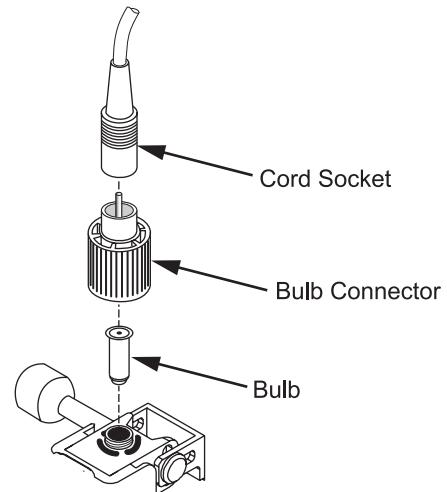
The bulb and bulb connector may be hot, and can burn your fingers.

CAUTION

Do not touch the glass part of the new bulb directly with your fingers. Oil from fingers can dramatically reduce bulb life.

4. Clean the new bulb with a soft, clean cloth.
5. Insert the new bulb so its locating pin engages in the housing slit.
6. Rest the bulb connector on the base of the bulb and firmly screw it in.
7. Re-connect the cord socket.

Figure 6-6 *PurePoint® LIO* Bulb Replacement



Calibration

Alcon recommends that the LIO be calibrated on an annual basis as an integral part of the laser system with which it is used. Refer to Section Four for calibration information.

PurePoint® LIO SPARE PARTS AND ACCESSORIES

| | |
|--------------------------------|------------------|
| Bulb 6V | P/N 542-1119-001 |
| Laser Protective Eyewear | P/N 8065750107 |
| 28 D Lens | P/N 8065750158 |
| 20 D Lens | P/N 8065-6879-01 |
| +2 D Ocular Lens | P/N 301-361 |
| 0 D Ocular Lens | P/N 301-362 |
| Headset Stand | P/N 8065750891 |

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